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(71) Applicant (for all designated States except US): VIVANT MEDICAL, INC. [US/US]; 3210B Alpine Road, Portola Valley, CA 94028 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SIRIMANNE, D., Laksen [LK/US]; 111 El Carmelo Avenue, Palo Alto, CA 94306 (US). SUTTON, Douglas, S. [US/US]; 1595 Adobe Drive, Pacifica, CA 94044 (US). FAWZI, Natalie, V. [US/US]; 14 Somerset Court, Belmont, CA 94002 (US). BUSH, Mary, Elizabeth [US/US]; 2068 Mento Drive, Fremont, CA 94539 (US). MOORMAN, Jack, W. [US/US]; 136 Pinta Court, Los Gatos, CA 95030 (US).

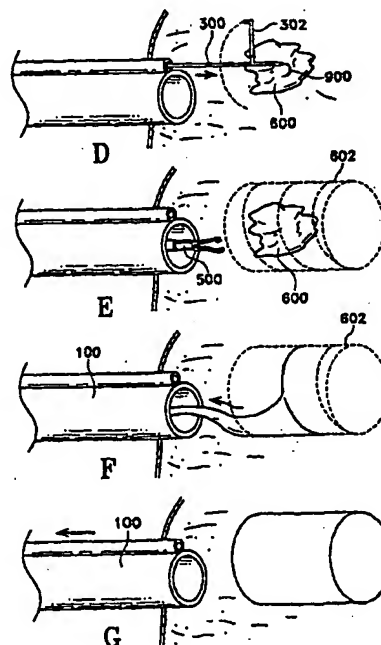
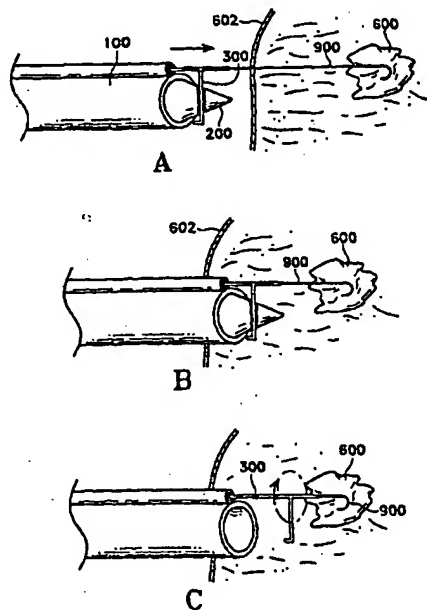
(74) Agents: REVELO, William, C. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).

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(54) Title: PERCUTANEOUS TISSUE REMOVAL DEVICE



(57) Abstract

This is a device for percutaneous tissue sampling or excision. In particular, it uses a rotating cutter which produces a helically cut, discrete tissue mass that is removable through a comparatively much smaller access member. The tissue mass is easily reconstructed to its original form and orientation once taken from the body for further study.

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PERCUTANEOUS TISSUE REMOVAL DEVICE

RELATED APPLICATION

This is a continuation in part of U.S. Ser. No. 09/145,487, filed September 1, 1998, now pending, the entirety of which is incorporated by reference.

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FIELD OF THE INVENTION

This invention relates to a device and to a related procedure for percutaneous tissue sampling or excision. In particular, it uses a rotating cutter which produces a helically cut, discrete tissue mass that is removable through a comparatively much smaller tissue access device. The tissue mass is easily reconstructed to its original form and orientation once taken from the body for further study.

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BACKGROUND OF THE INVENTION

Despite the advances made in technologies such as medical imaging to assist the physician in early stage diagnosis and treatment of patients with possible atypical tissue such as cancer, it is still often necessary to sample difficult-to-reach organ or tissue lesions by biopsy to confirm the presence or absence of abnormalities or disease.

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A disease for which biopsy is a critical tool is breast cancer. This affliction is responsible for 18% of all cancer deaths in women and is the leading cause of death among women aged 40 to 55. As with many diseases and other types of cancer, early detection and diagnosis of breast cancer is critical in providing the best chance of survival.

20

In the majority of cases, detection of the disease is first made when a patient discovers a palpable mass through self-examination and consults her physician. For breast lesions that are more difficult or impossible to detect through palpation, diagnostic techniques such as x-ray mammography and, more recently, digital mammography, and scintimammography are invaluable. Other techniques such as ultrasound, magnetic resonance, the Dilon gamma camera, position emission tomography, MIBI, computed topography, fluoroscopy, thermography, transillumination and diaphanography can also be used to help determine the presence and nature of suspect tissue.

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Of these technologies, the primary clinical diagnostic tool for the detection of breast cancer is x-ray mammography. Over 15 million mammograms are performed each year in

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the United States alone. Mammography uses x-rays to image breast tissue, identifying areas of high density as possible lesions.

Unfortunately, the limitations of technologies such as mammography in accurately detecting precancerous or cancerous lesions in the breast are significant. Among these limitations is the fact that only one out of every five lesions discovered through x-ray mammography proves to be cancerous. Roughly 25% of women have dense breast tissue, which is notoriously difficult to inspect via mammography. Also, mammography is generally less effective for women under 40 years of age. For younger women, therefore, self-examination for palpable lesions or ultrasound examination is important. However, neither of these techniques is able to detect microcalcifications, important possible precursors to cancer.

As long as there is a degree of uncertainty associated with these various diagnostic techniques, biopsies must be performed to sample the suspicious tissue to determine its exact nature and pathology.

In the detection and treatment of breast cancer, there are two general classes of biopsy: the minimally invasive percutaneous fine or core needle biopsy and the more invasive surgical or "open" biopsy.

Open biopsies, both incisional and excisional, are advisable when suspicious lumps should be removed in their entirety or when core needle biopsies don't give complete information about the nature of the lesion.

One such type of open biopsy is the wire localization biopsy. Such a procedure includes the following steps: first, a radiologist inserts a wire into the breast under x-ray guidance to mark the location of the suspect tissue. The tissue is then removed by a surgeon for examination by a pathologist. Although large tissue samples are removed by this technique, the risk of permanent disfigurement, the attendant morbidity and mortality risks associated with surgery, and long hospital recovery times are but three of the many disadvantages associated with open surgical biopsies.

Of the less invasive class of percutaneous biopsies, the least invasive is known as a fine needle aspiration biopsy (FNAB). For palpable lumps, a physician inserts a needle attached to a syringe directly into the lump to obtain a cell sample, which is then examined by a cytologist. For non-palpable lesions identified by x-ray mammography or other diagnostic tool, fine needle aspiration biopsies are often performed under stereotactic or

ultrasonic guidance. Under stereotactic guidance, multiple mammograms are taken of the breast under compression and the images are analyzed by a computer to determine the location of the suspect lesion in three dimensions. The physician then penetrates the breast with a needle, targeting the suspect region and removing a small number of cells.

5 Alternatively, in the case of a nonpalpable mass, ultrasound may be used to guide the FNAB in real time in a noncompressed breast. There are two significant drawbacks to fine needle aspiration biopsy: first, several specimens must be taken to ensure the lesion is well-sampled. Secondly, the limited size of the specimens obtained under fine needle aspiration biopsy dictate that a skilled cytologist be involved to analyze the suspect cells out of
10 context of the surrounding healthy tissue. Success varies widely. False negatives have been reported to vary from 1 to 31%, and false positives from 0 to 11%.

A second type of percutaneous needle biopsy used to obtain a larger specimen is known as a core needle biopsy. With this procedure, a larger needle, such as the Tru-Cut needle, is inserted into the breast via an incision in the skin with or without the aid of
15 stereotactic or ultrasonic guidance. A coring needle, which may be spring-loaded, is then inserted into the breast to obtain a single core sample of tissue, preferably through the center of the lesion. The larger specimen obtained by this technique can be more accurately read by a pathologist, who can analyze the suspect cells in the context of the surrounding tissue. Examples of such devices are described in U.S. Patent No. Re. 34,056
20 and U.S. Patent Nos. 4,944,308 and 4,953,558.

Traditionally, as with fine needle aspiration biopsies, core biopsies require multiple core samples, typically four to twenty, to ensure an accurately representative sample of the suspect region is profiled. This means that as many as twenty separate needle insertions must be made into the breast through the skin.

25 More recently developed needle biopsy technologies are directed to solving this problem by allowing multiple samples to be obtained through a single incision, such as that described in U.S. Patent Nos. 5,709,697 and 5,782,775. One such technology, described in U.S. Patent Nos. 5,526,822, 5,769,086, and 5,775,333, utilizes a trocar-tipped probe, which is positioned in the breast under stereotactic or ultrasonic guidance to align the suspect
30 lesion with an aperture that extends along a specified length of the probe. The tissue is then sucked into the aperture wherein a rotating cutter in the probe is advanced distally to cut and capture tissue specimen into the probe lumen. The cutter is then withdrawn,

transporting the specimen to a tissue collection chamber. Next, the probe, which is still in the breast, is radially rotated in position through a desired angle to align the aperture with another target tissue area. The steps of rotation, cutting, and collection, which can be automated and assisted by vacuum, are repeated until the desired number of samples is obtained.

Although this type of device requires only a small, single incision to obtain a number of core samples, each sample is still limited in size, requiring excision of multiple specimens for accurate pathologic diagnosis. As with other percutaneous excisional devices in which multiple specimens must be obtained, it is often difficult to reconstruct the spatial location and orientation of the suspect tissue as it resided in the breast prior to excision, resulting in a concomitantly difficult pathological analysis. In fact, because of the difficulty of reconstructing the biopsy samples, pathologists will assume that any cancer found in the tissue sample had a dirty margin.

Another type of percutaneous excisional breast biopsy device designed to obtain a single suspect tissue sample up to 20 mm in diameter is generally described in U.S. Patent Nos. 5,111,828, 5,197,484, and 5,353,804. This device, however, requires the use of a relatively large diameter cannula to obtain an adequate specimen size.

What is needed is a small-diameter percutaneous excisional biopsy device that allows a physician to obtain, in a minimally invasive manner, a relatively large tissue specimen through a small incision. Further, what is needed is a device that can obtain a specimen large enough for a complete, accurate and satisfactory pathologic determination, obviating the need for obtaining multiple core specimens and reconstructing them *ex vivo*.

SUMMARY OF THE INVENTION

This invention relates to devices and procedures for removing integral volumes of tissue via percutaneous access. The diameter of the volume removed using this invention is typically larger than the diameter of the access device. Depending upon the size of the device selected, the inventive device may be used for biopsy samples or for excision of larger amounts of tissue containing "suspicious areas" or tumorous masses. The tissue mass removed is typically continuous in form. Because of the method in which the device operates, the trauma caused by removal of the chosen volume is significantly lessened as compared to other available devices. The tissue mass removed is readily reassembled into

a discrete mass which has the same form and orientation as the mass had in the body.

The procedure involved the steps of selecting a target tissue mass. A trocar, tubular vessel removal member, and a cutting member are introduced percutaneously to the vicinity of the volume to be removed. The cutting member is positioned so that, as it is
5 advanced and turned (after the trocar is removed), the cutting member produces a generally cylindrical mass of tissue having a circular cut at the front and back end of the cylinder and a spiral cut through the cylinder. The spiral-cut cylinder may be removed after the cutting is completed or during the step of producing that spiral cut. The spirally cut tissue is preferably then reformed into its initial cylindrical shape for further analysis or pathology.
10 The step of cutting may be variously by the use of RF, ultrasound, or mechanical cutters, or by combinations of the three.

This procedure may be used in any internal, preferably soft, tissue, but is most useful in breast tissue, lung tissue, prostate tissue, lymph gland tissue, etc. Obviously, though, treatment and diagnosis of breast tissue problems forms the central theme of the
15 invention.

The components typically used in the inventive procedure include a tissue removal member typically having two lumens. The larger lumen is for the removal of excised tissue from the targeted body site and the smaller lumen, which need not be continuous but may be simply a positioner loop or the like, is used for positioning of the cutting member. A
20 trocar fits within the larger lumen in the tissue removal member and is used to penetrate the skin and tissue and thereby to position the distal end of the tubular tissue removal member in the vicinity of the tissue volume to be removed.

The cutting member has a long shaft that typically is placed within the smaller lumen of the tissue removal member. The cutting member is both advanced and rotated so
25 that a generally cylindrical mass of tissue is produced at the chosen site. The lesion or tumor "suspicious mass" is to be situated within that chosen cylindrical region.

The tissue, while it is being cut from or after it has been cut loose from the body by the cutting member is then removed through the large lumen of the tissue removal member, perhaps using an auger-like device to carry the tissue sample to an external collector.
30 Desirably, the removed tissue is placed in sample receptacle for later study.

Generally, the region to be excised is identified using stereotactic indexing apparatus as is well known in the art. It is typical that the rotation and advancement of the

cutting member is controlled using an automated controller box.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Figure 1 shows an assemblage of the components, as in a kit, which make up the inventive tissue removal device.

 Figures 2A to 2G show variations of the tissue removal member and their relation to the rotatable cutting member.

10 Figure 3 shows another variation of the tissue removal member, its associated tissue cutting member, and a desirable manner for transporting the accumulated tissue for later analysis.

 Figures 4A and 4B show, respectively, a partial cutaway side view and an end view of a variation of tissue removal member and in particular, show an augering device to assure orderly removal of the excised tissue from the target area.

15 Figure 5 shows another variation of the tissue auger in partial cutaway side view within the tissue removal member.

 Figure 6A shows a top view and Figure 6B shows a side view of a trocar which fits within the tissue removal member and supports the tissue cutting member as it is introduced into the target tissue region.

20 Figures 7A to 7D show variations of the shape of tissue cutter.

 Figures 8A to 11B show, variously, front quarter views and top views of configurations of the cutting members shown in Figures 7A to 7D.

 Figures 12A to 12B show a two-part expandable diameter cutting member and depict the steps of the cutting surface expansion.

25 Figure 13A shows a front quarter view, Figure 13B shows an end view, Figure 13C shows a side view, and Figure 13D shows a top view of an extendible mechanical cutting member.

 Figure 14A shows a front quarter view, Figure 14B shows an end view, and Figure 14C shows a side view of mechanical cutting member.

30 Figure 15A shows a front quarter view, Figure 15B shows an end view, and Figure 15C shows a side view of a cutting member having a two-part cutting surface which is extendable from the shaft of the cutting member. Figure 15D shows a typical cross-

section of the two part cutting surface.

Figure 16 shows a variation of the cutting member in which a mechanical cut is made using rotating, generally circular, blades.

5 Figure 17A is a front quarter view of a cutting member having a single leading cutting surface. Figure 17B is a cross-sectional view of the radial blade of the cutting member shown in Figure 17A showing the cutting angle.

Figure 18A is a front quarter view of a multiple blade, rotatable cutting member and Figure 18B is a partial cross-sectional view of the cutting surfaces for that cutting member.

10 Figure 19A is a side view of a typical endoscopic snare suitable for use in grasping the removed tissue in accordance with this invention. Figure 19B shows a harpoon spear which is also suitable for accessing and grabbing tissue for use in removing selected tissue when using this device. Figure 19C is an expandable braid and optional allied hook also suitable for retrieving tissue using this invention.

15 Figures 20A through 20G show a typical procedure sequence using the invention described herein and, in particular, the kit selection found in Figure 1.

Figures 21A through 21H show a variation of a typical procedure sequence using the invention described.

DESCRIPTION OF THE INVENTION

20 As noted above, this invention relates to devices and procedures for removing integral volumes of tissue, typically breast tissue, via percutaneous access. The diameter of the tissue volume removed using this invention is larger than the diameter of the access device. Depending upon the size of the device selected, the inventive device may be used for biopsy samples or for excision of larger amounts of tissue containing "suspicious areas"

25 or tumorous masses. Because of the method in which the device operates, the trauma caused by removal of the chosen volume is significantly lessened as compared to other available devices. In addition, the tissue mass removed can be readily assembled, after exit from the body, into a discrete mass that has the same form and orientation as the mass had in the body.

30 In general, the procedure involved is this: first, a target tissue mass is selected. A trocar, tubular vessel removal member, and a cutting member are assembled and introduced percutaneously to the vicinity of the volume to be removed. The cutting member is

positioned so that, as it is advanced and turned (after the trocar is removed), the cutting member produces a generally cylindrical mass of tissue having a circular cut at the front and back end of the cylinder and a spiral cut through the cylinder. The spiral cut cylinder may be removed as a continuous strip after the cutting is completed or during the step of producing that spiral cut. Alternatively, to prepare for pathology an essentially cylindrical biopsy sample that was obtained by a conventional coring method, a cutting member may be simultaneously rotated and translated with respect to the biopsy sample to helically cut the biopsy sample; this may be accomplished in several ways, such as by rotating and translating the biopsy sample, or by rotating and translating the cutting member, or by rotating one and translating the other, or by rotating the cutting member clockwise and the biopsy sample counterclockwise while translating one with respect to the other. The spirally cut tissue is preferably then reformed into its initial cylindrical shape for further analysis or pathology. The step of cutting may be variously by the use of RF, ultrasound, or by the use of mechanical cutters.

Figure 1 shows, in generic fashion, the components typically used in the inventive procedure. Tissue removal member (100) is shown in Figure 1 as typically having two lumens. The larger lumen is for the removal of excised tissue from the targeted body site and the smaller lumen is used for positioning of the cutting member (300), as will be discussed below. The trocar (200), which fits within the larger lumen in tissue removal member (100), is also shown. Trocar (200) is used to penetrate the skin and tissue and thereby to position the distal end of the tubular tissue removal member (100) in the region of the tissue volume to be removed.

Figure 1 shows a typical cutting member (300). Cutting member (300) has a long shaft that typically is placed within the smaller lumen of tissue removal member (100). The shaft is preferably hollow so as to allow it to follow a localization wire (900) that has been used to mark the tissue to be removed. When the cutting member (100) shaft is situated in the smaller lumen of tissue removal member (300), it is both advanced over the localization wire (900) and rotated about it so that a cylindrical mass of tissue is produced at the chosen site. The lesion or tumor is to be situated within that chosen cylindrical region.

The tissue, while or after it has been cut loose from the body by cutting member (300), is then removed, e.g., by a removal member (500) such as that shown in Figure 1.

Desirably, the removed tissue is placed in sample receptacle (700) for later study.

Generally, the region to be excised is identified using stereotactic indexing apparatus as is well known in the art. It is typical that the rotation and advancement of the cutting member (300) is controlled using a controller box (800) such as that depicted in Figure 1.

TISSUE REMOVAL MEMBER

Figure 2A shows a typical variation of the inventive tissue removal member (102). This variation includes a larger lumen member (104) and a smaller lumen member (106) that is exterior to the lumen (103) of large lumen member (104). For purposes of illustration only, a cutting member (108) is shown in the lumen (105) of small lumen member (106). Central to this invention is the concept that as the cutting member (108) is rotated by the physician user, it cuts a disc (or spiral as it is advanced) which is significantly larger in diameter than is the lumen (103) of large lumen member (104) of the tissue removal member (102).

In the inventive tissue removal members shown in Figure 2A and subsequent figures, the smaller lumen member carrying the cutting member may be fixed with respect to the larger lumen member. Alternatively, the smaller lumen member may translate with respect to the larger lumen member; the advantages of this will be seen with respect to Figure 2G and Figures 21A-G. Furthermore, the distal end of the smaller lumen member may be somewhat tapered or conical to aid in penetrating tissue.

Typically, large lumen member (104) is constructed from any of a large number of polymers typically used in this service, e.g., Nylons, reinforced Nylons, polyethylene, polypropylene, polyethylene terephthalate (PET), fluorocarbon plastics (e.g., Teflon), etc. The polymers may be reinforced by fibers or filled. As will also be discussed below, the tissue removal member may be reinforced or made radially expandable using coils or braids of metals, alloys, or polymers (natural or synthetic) included in the walls of the member. The walls may be made at least partially radio-opaque by introduction of, e.g., powdered tantalum, powdered tungsten, bismuth carbonate, and other known particulate and fibrous radio-opacifiers.

Figure 2B shows a similar tissue removal member (110). In this variation, the small

lumen tubular portion (112) is not exterior to the lumen (113) of large lumen member (114) but is instead within the large lumen member (114). Again, the rotating end rotatable cutting member (108) is shown positioned in the lumen (111) of small lumen tubular member (112). This variation has the obvious benefit of being somewhat smaller in overall diameter than is the variation shown in Figure 2A. However, the size of the cylinder that can be produced by the properly sized cutting member (108) is also somewhat smaller. This variation might, for instance, be better suited for gathering a biopsy sample than for performing a lumpectomy.

Figure 2C shows another variation in which the small lumen portion (116) of the tissue removal member (118) is spaced away from the interior wall of the large lumen (115). This variation is especially suitable for use with the helical tissue removal auger, which is discussed in significantly more detail below. It is also especially suitable for use with cutting members that expand or extend outwardly from that small lumen (116).

Figure 2D shows another variation of the tissue removal member (120). In this variation, the tubular portion of the outer member is elastically expandable. This is depicted by the expanded portion (122) shown in Figure 2D. An expandable outer tubular section is suitable with any of the variations described above. This variation, however, is expandable due to the use of a woven braid (124) and an elastomeric polymer forming the outer layer (126) of the device. An optional inner layer (128) is also depicted in Figure 2D but such an inner layer (128) is not, obviously, absolutely necessary. It is convenient and desirable, however. Figure 2D is a partial cutaway.

The expandable tissue removal member shown in Figure 2D is especially suitable for use with a cutting member (and its allied secondary or smaller tubular section (130)) that is significantly larger than the diameter of the outer tubing member. The whole cutting member and inner tubing may be urged through this expandable outer section for use at the chosen site.

Figures 2E-2G show variations of the inventive tissue removal member that include a cooling system for cooling or freezing tissue such as breast tissue or fat tissue. Cooling or freezing helps to physically stabilize the tissue during cutting to ease the cutting process and render a cleaner cut with less trauma to the surrounding tissue. It also helps to solidify the fat during cutting, whether using RF, ultrasound, a mechanical blade, or other cutting means. Cooling or freezing also helps to keep coagulum from forming on an RF or other

heat-producing cutting tool.

Figure 2E shows an inventive tissue removal member (180) having a closed system for cooling or freezing tissue. The large lumen member (181) has a U-shaped pipe (186) within the large lumen (181). Coolant flows through one leg of the pipe and returns
5 through the other. The arrows show the direction of coolant flow. Large lumen member (181) provides thermal insulation. The coolant-carrying pipe (186) is exposed to the tissue at the open distal end of large lumen member (181), allowing heat to be transferred from the tissue to the cooling pipe (186). The coolant-carrying pipe (186) can be removed following cutting so that excised tissue may be removed through the large lumen (181).

10 Figure 2F shows a variation of the inventive tubular tissue removal member (188) having an open system for cooling tissue. The large lumen member (190) has one or more small lumens (191) through its wall, through which a biocompatible coolant such as cold saline can be pushed into the tissue. The coolant and any melted fat or blood may be aspirated through the large lumen (189). This system may be used in procedures in which
15 the tissue removal occurs after all cutting is completed as well as in procedures in which the tissue is pulled into the tissue removal member (180) simultaneous with the cutting. The arrows show the preferred direction of coolant flow.

Figure 2G shows another variation of the inventive tubular tissue removal member (192) having an open system for cooling tissue. Small lumen member (196) translates with respect to large lumen member (194) so that its distal end is always close to the cutting end of the cutting member (300). The small lumen (195) is sized to accommodate cutting
20 member (300) with enough clearance to deliver biocompatible coolant through it to the tissue in the vicinity of the tissue being cut. The coolant and any melted fat or blood may be aspirated through the large lumen (193) of the large lumen member (194). The arrows
25 show the direction of coolant flow. It should be noted that suction may be applied as in either Figure 2F or 2G to remove melted fat, blood or other tissue or debris during the procedure, with or without cooling.

Figure 3 shows another variation of the inventive tubular tissue removal member (142), in this instance, having a center small tubing member (144). Of particular instance
30 in this variation is the presence of a receiver (146) situated at the proximal end of the tubular tissue removal member assembly (140).

Of special interest is the specimen collector (148), which may be fitted within

receiver (146). It is within the scope of this invention to index the position of the tissue cutting member (150), here depicted as a simple "squared-J" shape, with the position of the tissue collector (148) so that as the tissue is removed through the tubular tissue removal member (142), it ultimately resides in the tissue collector (148) in the very position as found in the chosen collection site within the body. A cap (152) for the tissue collector (148) is also shown.

Figure 4A shows a variation of the tubular tissue removal member (160) having an outer tubular member (162), an integral receiver (164), and a tissue displacement auger (166).

In this variation of the inventive device, the cutter member (168) rotates in one direction, e.g., clockwise, and the auger (166) rotates in the other direction, counter-clockwise. In this way, the excised tissue leaves the cutting surface as it is separated from the remaining tissue and is newly-deposited in the form as found in the body, in the receiver (164).

In general, the auger (166) maintains the integrity and continuity of the removed tissue by maintaining the separation of the turns of the tissue as it passes from the distal end of the tubular tissue removal member (160) to the proximal end. The auger (166) may be stationary as the cutter advances in the tissue member (168) if the tissue is pulled from the proximal end.

It may be apparent that the tissue removal member (160) may be advanced (or stationary) as the cutting member (168) progresses spirally through the tissue to be excised. In many instances, movement is not necessary, however.

Figure 4B shows an end view of the device found in Figure 4A. In it may be seen the cutting member (168); which cutting member has a significantly larger diameter as it rotates than does the inner diameter of tubing member (162). The leading edge of auger (166) may also be seen in Figure 4B.

The diameter of auger (166) in this instance is fairly close in size to the inner diameter of outer tubing member (162). This tight clearance is not, however, necessary. For instance, Figure 5 shows a tubular tissue removal member having an auger (168) with vanes (170) having a significantly smaller diameter. Auger (168) provides a significant clearance between the tip of the vanes (170) and the interior lumen of outer tubular member (172). In some instances, it may be desirable to use a smaller diameter auger so to allow

for, for instance, a grasping device to slide between the auger and the interior of the wall, to grasp the tissue as it comes off the cutter, and to urge the excised tissue towards the proximal end of the tubular tissue removal member.

5

TROCAR

The trocar used in this assemblage is preferably one that fits within the inner lumen of the tubular tissue removal member. This permits the trocar to carry that member as it penetrates the outer skin and the tissue on the pathway to the selected site. The trocar used in this invention may simply be one having a sharp mechanical cutting surface or may be
10 connected to one of any of known RF sources which generates energy for cutting tissue and, perhaps, cauterizing it as the initial incision is made.

Figures 6A-6B show a typical, but highly desirable, variation of a trocar (200) that is especially suitable for use in this assembly. Specifically, trocar (200) has a sharp leading pointed end (202), a sharp cutting edge (204) and, desirably, a transverse slot (206) for
15 carrying the cutting member to the selected tissue site.

CUTTING MEMBER

The cutting members discussed herein are all similar in that each has a cutting surface, i.e., the portion of the device that meets the tissue and cuts a path whether that path
20 is made by a mechanical cutter as with a knife blade or by an RF or ultrasound energy source. The cutting member may be attached to an RF or ultrasound source or may be made up of mechanical cutters or may be combinations of them. Often, the members are mechanically vibrated to produce a cutting motion. It is within the scope of this invention that the tissue itself be vibrated to produce a differential motion between the tissue and the
25 cutting surface to create a mechanical cutting motion.

The cutting member preferably includes a hollow shaft that allows it to follow a localization wire used for marking the tissue to be removed. This hollow shaft is preferably electrically and thermally insulated from the localization wire, especially when an RF, ultrasound, or other similar cutter is used. The insulation may take the form of an insulated
30 coating on the inside of the hollow cutter shaft or on the outside of the localization wire. Alternatively or additionally, the entire cutter shaft or localization wire may consist essentially of an electrically and/or thermally insulating material.

Figures 7A, 7B, and 7C schematically depict three shapes especially suitable for use as RF cutters. The tissue cutting member shape (300) shown in Figure 7A is generally referred to as the "L" shape. The cutting member has a shaft (302) and a radial member (304) and a very short axial cutting length (306). This shape is especially suitable when the pitch of the desired helix made in the chosen tissue, is quite small. The pitch of the cut helix should be no smaller than the length of axial cutting section (306).

Figure 7B shows a similar cutting member (310) also having a radial cutting surface (312) and an axial cutting surface (314). This shape is known as a "squared-J."

Figure 7C shows a "rounded-J" shaped cutting member (316). It also has an axial cutting surface (318). The radial cutting surface (320) is rounded.

Especially suitable for this service is the squared-J shaped cutting member (322) with a distal extension (324) as shown in Figure 7D. We have found that occasionally when approaching the boundary of lesions within, e.g., breast tissue, the cutting member variations shown in Figures 7A, 7B, and 7C may stray from the directed path. Distal extension (324) serves as an axial leader or guide and prevents any tendency of the cutter to wander or, indeed, to stop the tissue from being pushed away from the cutter. To further stabilize the movement of the cutter, it is sometimes desirable to insulate distal extension (324) with insulation (326) proximal of the tip (328) so to prevent enlargement by heating of the track that has been produced by the distal extension. In a cutting member having a distal extension (324), a localization wire may be used to further stabilize and guide the cutting member to the lesion. In the case where the cutting member follows the wire, the lumen of the hollow shaft may extend through the distal extension (324), with the distal tip (328) being open to the shaft lumen.

Figures 8A through 11B show shapes that are appropriate for tissue cutting members used in accordance with this invention when RF is applied to the cutter as the cutting energy.

Figures 8A and Figure 8B show a simple round wire for the cutting member. Figure 9A and 9B show a cutting member having a rectangular cross-section (332). Figures 10A and 10B show cross-section (334) having a knife edge (336). A sharpened knife edge such as (336) will focus the RF energy towards the leading edge of the cutting surface and facilitate movement of the device through the tissue. Again, it is within the scope of this invention that this variation of the invention be used as a combination

mechanical and RF cutter. Similarly, Figures 11A and 11B show a cross-section (338) that also has a serrated knife edge (340). The further limitation of surface area on the leading edge of the cutting member enhances the use of RF in the cutting member of the invented device.

5 The material making up the cutting members shown in Figures 7A through 11B is not central to this invention. The materials may be any of a variety of stainless steels, cobalt alloys, and other alloys typically used in this service.

 Nonetheless, we have found that certain titanium-nickel alloys are particularly suitable for use with this device, particularly when the blades are used either as simple
10 knife-edge cutters or as a combination of RF/mechanical cutters. This material is typically a 50/50 molar ratio alloy of titanium and nickel. Closely related alloys are the shape memory alloys that exhibit superelastic/pseudoelastic shape recovery characteristics. These alloys are well-known and are commonly referred to as "nitinol." See, for instance, U.S. Patent Nos. 3,174,851; 3,351,463; as well as 3,753,700. These alloys are characterized by
15 their ability to be transformed from an austenitic crystal structure to a stress-induced martensitic (SIM) structure at certain temperatures, and return elastically to the austenitic shape when the stress is removed. These alternating crystalline properties provide the alloy with its superelastic properties. The nitinol forms of these alloys are readily commercially available and typically will undergo the austenite-SIM-austenite transformation at a variety
20 of temperature ranges between -20 C and 30 C.

 Figures 12A through 12D show a cutting member that is extendable from a delivery shape (as shown in Figure 12A) to a fully extended and deployed shape (as shown in Figure 12D). The cutting surface of this particular variation is desirably a superelastic alloy because of difficulty of unfolding the device without inducing strain upon the cutting
25 member material.

 Figure 12A shows device as delivered through the small lumen tubular member discussed above. The cutting member assemblage (350) has an outer tubing member (352) and a window (354) for exiting of cutting surface member (356). Cutting member (356) is slidably extendable through the lumen of cutting tubular member (352).

30 Figure 12B shows cutting member (356) emerging from window (354).

 Figure 12C shows the further emergence of cutting member (356) and Figure 12D shows cutting member (356) fully emerged from cutting member shaft (352).

This variation of the invention allows the use of a fairly large diameter cutting member, e.g., one having a cutting radius (358) which is more than the overall outside diameter of the tubular tissue removal member for which it is deployed.

Figure 13A shows a tissue cutting member (360) that is used primarily for
5 mechanical cutting although it obviously may be used as a combination of RF and mechanical cutter as well. We have observed that in the tissue found in the breast, cutting is facilitated by using a cutting surface at a nonperpendicular angle to the path of the cutter. When cutting a circle in tissue by rotating cutting member (360), cutting surface (362), which lies on a radius of the circle to be cut, is less effective than cutting surface (364),
10 which does not lie on a radius. Cutting surface (364) provides an angular surface to the direction of cutting; that is, cutting surface (364) is not parallel to the shaft of cutting member (360), but is skew to it. As noted above, this device may be vibrated or the tissue to be removed may be vibrated to provide additional cutting action. A cutting surface that is pointed or serrated is also desirable.

15 Figure 13B shows an end view of the cutting member and the end cutting surface (362). Figure 13C shows a side view of the cutting member (360), while Figure 13D shows a top view of the same.

Figure 14A shows another variation of the mechanical cutting member (370). Each of the radially extending blades (372) and axially extending blades (374) has a triangular
20 shape with a leading edge (376) which is positioned so to present an angular cutting surface to the tissue to be excised. As may be seen in Figures 14B and 14C, the triangular cutting blades have points (378) and (380), which serve to enhance the cutting capabilities of the depicted cutting member (370).

Figures 15A through 15D show an extendable cutting member (390). The cutting
25 member (390) is made up of three members: a housing member (392), a guide track (394), and a cutting member (396). Guide member (394) and cutting member (396) are shown extended from the housing (392) in each of Figures 15A, 15B, and 15C. However, as is noted by the arrow in Figure 15A, the guide member (394) and cutting member (396) are extended from the housing. Such extensions are done upon arrival of the device at the
30 selected excision area. Desirably, the blade or cutting member (396) is made of a sharpened superelastic alloy of the type discussed above. Similarly, a guide member (394) is also so constructed. This allows the blade and guide to be extended from the housing

(392) and retain a desired shape upon that extension. The blade member (396) is desirably oscillated in a saw-like fashion as depicted in Figure 15A as shown by the arrows in Figure 15A.

Figure 15B shows an end view of the cutting member. Figure 15C shows a side view of the tissue cutting member (390). It may be observed that the tip of cutting member (396) is extendable past the tip of carrier (394). This allows a cut to be made during each bit of the oscillatory travel of cutting blade (396).

Figure 15D shows, in cross-section, the relationship between carrier (394) and cutting blade (396). The cutting surface (398) is also depicted in this cross-sectional view.

The tissue mass removed by this curved blade is obviously not a cylindrical section as that term is used with respect to the devices and variations found above. The section or mass removed by this variation of the invention is respectively concave at one end and convex at the other. Nevertheless, other shapes that are deployable in this fashion are also contemplated.

Figure 16 shows a version of the invention (400) which the axial cutting members (402) and the radial cutting member (404) are moving as by rotating. Shaft (406) contains a small drive cable that engages a hub on the rotating blades (402) and (404).

Figure 17A depicts a tissue cutting member (410) having a straightforward radial cutting blade (412) and an axial cutting blade (414). The variation depicted in Figure 17 may be oscillated to enhance its cutting capabilities or may be imbued with RF or ultrasound energy as well. Figure 17B shows a cross-section of the device shown in Figure 17A. The angle (α) of cutting blade (415) as mounted on shaft (417) may range in value from 90° to 165° or so depending upon physical considerations such as, e.g., the size of the large lumen in the tissue removal member -- the smaller the lumen, the thinner the tissue spiral should be, the smaller the angle (α) should be.

Figures 18A and 18B show a variation of the cutting member (416) which includes a double-bladed cutting surface on both the axial cutting member (418) and the radial cutting member (420). This variation, the details of the cross-section of which are better depicted in Figure 18B, has a leading cutting surface (422) and a trailing cutting surface (424). They are separated by a modest gap (426).

TISSUE MANIPULATION DEVICES

Figures 19A through 19C show tissue manipulation devices as may be used in conjunction with the overall assembly. In some instances, it may be desirable to grasp the initial portion of excised tissue so to guide it through the tissue removal member.

5 Depending on which of the configurations of tissue removal member is selected, a choice of one of the noted devices may be appropriate.

Figure 19A shows a simple endoscopic grasping device (500) that is readily available on the commercial market. Movement of the scissors-like handle produces a corresponding movement on the grasping tongs (504).

10 Figure 19B shows a tissue manipulation device (506) having a small wire-like shaft (508) and a harpoon-like end (510). For the purposes of completeness only, a manipulation knob (512) is also included for view. This picklike variation (506) is significantly flexible and may be used in, e.g., the auger tissue removal devices described above to ensure that the tissue in fact engages the interior of the auger and is removed as the auger turns.

15 Figure 19C shows a combination of braided grasper (520) and a hook component (522). The braided tissue snaring device (520) includes a distal woven braid section (524) that is easily manipulated by the two control wires or rods (526) and (528). If necessary, hook (522) is used to pull the excised tissue into braided cage (524). The two control wires (526) and (528) are used to either expand the diameter of braided cage (524) or to make
20 that diameter smaller. Once the tissue is at least partially within the braided cage (524), the device is removed from the lumen of the tissue removal device.

Other devices for removing excised tissue from the selected site would certainly be appropriate. For example, suction may be applied through the large lumen alone or in conjunction with another tissue-removal device. Furthermore, a vacuum may be applied
25 through a separate suction tool placed through the large lumen.

PROCEDURE FOR USE

Figures 20A through 20G show a generic method for using the tissue removal assembly of this invention. For the purposes of description here, this description assumes
30 that the user is removing a lesion found in breast tissue. The lesion (600) is found behind skin surface (602), and has been marked with a localization wire (900). Surrounding tissue is also shown. The generic device found in Figure 1 is used for purposes of this

description. The use, however, according to this invention is not significantly different when other variations of the device are used.

Figure 20A shows the assembled device ready for introduction to the skin surface. Shown is the tissue removal member (100) and trocar (200) with the nestled cutting member (300) residing in the transverse slot found in trocar (200). Cutting member (300) preferably has a hollow shaft, which is placed over localization wire (900). The device is positioned at the skin surface so that when a complete rotation of the cutting member (300) is had, the lesion (600) is within that circumference.

Figure 20B shows the assembled device after it has penetrated the skin surface (602) and is approaching lesion (600).

Figure 20C shows the initial entry of the cutting member (300) into lesion (600). This variation shows the use of an RF powered cutting member (300). A mechanical or ultrasound cutter may obviously be employed as well or instead of an RF style cutter (300). The cutting member (300) is first rotated so to form a circular cut proximal of lesion (600). This circular cut will form the proximal end of the cylinder of tissue that is ultimately removed. As shown, the lumen of cutting member (300) is sized to accommodate the localization wire (900) and track it to the lesion (600). The cutting member (300) remains centered about the localization wire (900), ensuring that the cylinder of tissue ultimately removed contains the end of the localization wire, and therefore, the lesion (600). This represents a significant advantage over prior art devices that have large lumens that follow a localization wire, wherein the wire does not stay centered within the lumen. Furthermore, in these prior art devices, because the localization wire is not supported in the region to be cut, the compression of the tissue by the cutter may cause the wire to buckle. In the inventive device, the hollow shaft of the cutting member (300) supports the localization wire (900) from the outside and prevents it from buckling under compression.

Figure 20D then depicts the axial movement of the cutting member (300) and the spiral shape of the cut as the cutting member (300) is rotated until the radial portion (302) is past lesion (600).

Figure 20E shows the introduction of grasping member (500) to the proximal end of the cylindrical tissue mass (602) containing lesion (600).

Figure 20F shows the removal of the helically cut tissue of cylindrical tissue mass (602) through the large lumen of tissue removal of member (100). Tissue removal may be

accomplished using the grasping member (500) or using suction applied through the large lumen, or the combination of both grasping and suction. The localization wire (900), if used, may be removed along with the tissue, and may, in fact, aid in removing the tissue. The large lumen may be used to pack the remaining cavity with, e.g., inert packing material such as carbon.

Figure 20G shows the removal of tissue removal member (100) from the breast.

Figures 21A through 21H show an alternative method for using the tissue removal assembly of this invention. As before, the lesion (600) is found behind skin surface (602), and has been marked with a localization wire (900). However, in this case, smaller lumen member (106), which carries a deployable cutting member (300), can translate with respect to larger lumen member (104).

Figure 21A shows a tissue removal member (100) and trocar (200) with a deployable cutting member (300) protruding out of the smaller lumen (105) of smaller lumen member (106). Cutting member (300) has a hollow shaft, which is ready to be installed over localization wire (900).

Figure 21B shows the tissue removal assembly with localization wire (900) partially inserted into the hollow shaft of cutting member (300).

Figure 21C shows the assembled device ready for introduction to the skin surface (602). The cutting surface of deployable cutting member (300) has been straightened and inserted into the smaller lumen (105) of smaller lumen member (106). The distal end of localization wire (900) is partially within the hollow shaft of cutting member (300), which is within smaller lumen member (106).

Figure 21D shows the assembled device after it has penetrated the skin surface (602) and is approaching lesion (600).

Figure 21E shows smaller lumen member (106) penetrating lesion (600) and continuing until it is just past the lesion. Smaller lumen member (106) has a slightly tapered or conical shaped distal end (107) to aid in penetrating the tissue. Cutting member (300) is still residing (hidden) within smaller lumen member (106).

Figure 21F shows the distal end of cutting member (300) emerging from smaller lumen member (106) and deployed to take on a squared-J shape distal of lesion (600). This may be done by pushing the cutting member (300) out of smaller lumen member (106) or by slightly retracting smaller lumen member (106), or both. Although not shown, it should

be noted that if smaller lumen member (106) is be retracted slightly to aid in deploying cutting member (300), member (106) may then be pushed slightly forward again following cutting member deployment to aid in supporting the cutting member during cutting.

Figure 21G shows the initial cut of the cutting member (300) distal of lesion (600).

5 The cutting member (300) is first rotated so to form a circular cut (604) distal of lesion (600). This circular cut will form the distal end of the cylinder of tissue that is ultimately removed.

Figure 21H then depicts the axial movement of the cutting member (300) and smaller lumen member (106), and the spiral shape of the cut as the cutting member (300) is rotated until the radial portion (802) is proximal of lesion (600). It should be noted that once cutting member (300) is deployed distal of lesion (600), smaller lumen member (106) may be fully retracted to its initial position; alternatively, once cutting member (300) is deployed, smaller lumen member (106) may be retracted as cutting member (300) is retracted. Once the cutter has reached the most proximal portion to be cut, axial movement is stopped long enough to make a radial cut to sever the proximal end of the sample. The cutting member (300) may optionally be retracted back into smaller lumen member (106).

One advantage of the method shown in Figures 21A-21H and described herein is that the cutting action occurs while pulling cutting member (300) toward the physician instead of while pushing it into the tissue.

20 Following the spiral cut, tissue is removed as previously described. In procedures that use a localization wire, such as those described with respect to Figures 20A-20G and 21A-21H, the localization wire may be straight or may have a "J" or other shape on its distal end. This shaped or angled distal end may be straightened so that it may enter the shaft of the cutting member. Alternatively, the distal end of the localization wire may be placed slightly distal of lesion (600); and the discrete tissue mass may be excised from a position slightly proximal of the localization wire distal end. In that case, the localization wire distal end (e.g., the "J"-shaped portion) never has to enter the cutting member hollow shaft.

30 The invention herein has been described by examples and a particularly desired way of practicing the invention has been described. However, the invention as claimed herein is not loaded to that specific description in any manner. Equivalence to the description as hereinafter claimed is considered to be within the scope of protection of this patent.

WE CLAIM AS OUR INVENTION:

1. A tissue removal assembly having a proximal end and a distal end, comprising:
 - 5 a.) a tubular tissue removal member having a wall, a distal diameter, a proximal end, a distal end, and a longitudinal axis extending between said proximal end and said distal end; an open, distally located tissue entry opening; a relatively more proximal, tissue exit port; and a tissue removal passageway extending between said tissue entry opening and said tissue exit port;
 - 10 b.) a cutting member, rotatable with respect to said tubular tissue removal member in a diameter greater than the tubular tissue removal member distal diameter, extendible beyond said distally located tissue entry opening, and having a cutting surface, where upon rotation of said cutting member and extension of said cutting member
 - 15 distally beyond said tissue entry opening within a tissue region, said cutting surface cuts a discrete tissue mass having an overall diameter measured generally orthogonal to the tubular tissue removal member axis which is greater than said tubular tissue removal member distal diameter and which discrete tissue mass is in a configuration removable through said tissue entry opening.
 - 20
2. The tissue removal assembly of claim 1 wherein said cutting surface is configured to cut a radial, helical path through discrete tissue mass.
3. The tissue removal assembly of claim 1 wherein said cutting member is manually
- 25 manipulatable from the proximal end of said tubular tissue removal member.
4. The tissue removal assembly of claim 1 wherein said cutting member has a generally rounded "J" shape.
- 30 5. The tissue removal assembly of claim 1 wherein said cutting member has a generally squared "J" shape.
6. The tissue removal assembly of claim 1 wherein said cutting member has an "L"

shape.

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7. The tissue removal assembly of claim 1 wherein said cutting member has an axis of rotation and a distal extension along said axis of rotation.

8. The tissue removal assembly of claim 1 wherein said cutting member is at least partially radio-opaque.

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9. The tissue removal assembly of claim 7 wherein said cutting member is at least partially radio-opaque.

10. The tissue removal assembly of claim 7 wherein said cutting member distal extension is at least partially radio-opaque.

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11. The tissue removal assembly of claim 1 wherein said cutting member is a wire cutting member.

12. The tissue removal assembly of claim 1 wherein said cutting member is a ribbon cutting member.

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13. The tissue removal assembly of claim 1 wherein said cutting member comprises a material selected from the group consisting of titanium, nickel, stainless steel, cobalt, tantalum, and mixtures and alloys thereof.

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14. The tissue removal assembly of claim 1 wherein said cutting member comprises titanium and nickel.

15. The tissue removal assembly of claim 1 wherein said cutting member is an RF cutter utilizing radio-frequency energy to cut said discrete tissue mass.

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16. The tissue removal assembly of claim 15 further comprising an RF source connected to said cutting member which is suitable for cutting said discrete tissue mass.

17. The tissue removal assembly of claim 1 wherein said cutting member is a mechanical blade.
- 5 18. The tissue removal assembly of claim 17 wherein said mechanical blade cutting member is vibrated.
19. The tissue removal assembly of claim 1 wherein said cutting member is an RF cutter having a sharp mechanical cutting surface.
- 10 20. The tissue removal assembly of claim 1 wherein said cutting member is an ultrasound cutter utilizing high frequency audio energy to cut said discrete tissue mass.
- 15 21. The tissue removal assembly of claim 20 further comprising an ultrasound source connected to said cutting member which is suitable for cutting said discrete tissue mass.
- 20 22. The tissue removal assembly of claim 1 wherein said tubular tissue removal member further includes a shaft passageway generally parallel to said tubular tissue removal member longitudinal axis and said cutting member includes a shaft extending between said cutting surface and said tubular tissue removal member proximal end and is slideable within and rotatable within said shaft passageway to advance said cutting surface.
- 25 23. The tissue removal assembly of claim 1 wherein said tubular tissue removal member further includes a shaft passageway interior to said tissue removal passageway and generally parallel to said tubular tissue removal member longitudinal axis and said cutting member includes a shaft extending between said cutting surface and said tubular tissue removal member proximal end and is slideable within and rotatable
- 30 within said shaft passageway to advance said cutting surface.
24. The tissue removal assembly of claim 1 further comprising a pick locatable within said

tissue removal passageway which pick is configured for removing said discrete tissue mass.

- 5 25. The tissue removal assembly of claim 1 further comprising a manipulatable grasping tool locatable within said tissue removal passageway which grasping tool is configured for removing said discrete tissue mass.
- 10 26. The tissue removal assembly of claim 25 wherein said manipulatable grasping tool comprises a pair of opposing jaws suitable for grasping said discrete tissue mass.
27. The tissue removal assembly of claim 25 wherein said manipulatable grasping tool comprises a grasping braid suitable for grasping said discrete tissue mass.
- 15 28. The tissue removal assembly of claim 1 further comprising a manipulatable suction tool locatable within said tissue removal passageway which suction tool is configured for removing said discrete tissue mass.
- 20 29. The tissue removal assembly of claim 1 further comprising a trocar sized to fit within said tissue removal passageway.
30. The tissue removal assembly of claim 29 wherein said trocar includes a slot and said cutting surface fits in said trocar slot.
- 25 31. The tissue removal assembly of claim 29 wherein said trocar is extendible distally though said tissue entry opening.
32. The tissue removal assembly of claim 1 wherein said tissue entry opening is open along the axis of said tubular tissue removal member.
- 30 33. The tissue removal assembly of claim 1 wherein said tissue entry opening is open generally perpendicular to the axis of said tubular tissue removal member.

34. The tissue removal assembly of claim 1 further comprising a rotatable auger situated within said tubular tissue removal member for moving excised tissue along said tubular tissue removal member to said tissue exit port.

5 35. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

introducing a tissue removal assembly to a region adjacent a selected internal tissue region, said tissue removal assembly comprising:

10 a.) a tubular tissue removal member having a wall, a distal diameter, a proximal end, a distal end and a longitudinal axis extending between said proximal end and said distal end; an open, distally located tissue entry opening; a relatively more proximal, tissue exit port; and a tissue removal passageway extending
15 between said tissue entry opening and said tissue exit port,

b.) a cutting member, rotatable with respect to said tubular tissue removal member in a diameter greater than the tubular tissue removal member distal diameter, extendible beyond said distally located tissue entry opening, and having a
20 cutting surface, where upon rotation of said cutting member and extension of said cutting member distally beyond said tissue entry opening within said tissue region, said cutting surface cuts a discrete tissue mass having an overall diameter measured generally orthogonal to the tubular tissue removal member axis which is greater than said tubular tissue removal member distal diameter
25 and which discrete tissue mass is in a configuration removable through said tissue entry opening,

rotating said cutting member and said cutting surface to form a discrete tissue mass having an overall diameter measured generally orthogonal to the tubular tissue removal
30 member axis which is greater than said tubular tissue removal member distal diameter and which discrete tissue mass is in a configuration removable through said tissue entry opening, and

removing said discrete tissue mass through said tissue entry opening, through said tissue removal passageway, and out through said tissue exit port.

- 5 36. The procedure of claim 35 wherein the cutting member is rotated to form a helical cut in said discrete tissue mass.
37. The procedure of claim 35 wherein said cutting member has a generally rounded "J" shape.
- 10 38. The procedure of claim 35 wherein said cutting member has a generally squared "J" shape.
39. The procedure of claim 35 wherein said cutting member has an "L" shape.
- 15 40. The procedure of claim 35 wherein said cutting member has an axis of rotation and a distal extension along said axis of rotation.
41. The procedure of claim 35 wherein said cutting member is at least partially radio-
- 20 opaque.
42. The procedure of claim 35 wherein said cutting member is a wire cutting member.
43. The procedure of claim 35 wherein said cutting member comprises a material selected
- 25 from the group consisting of titanium, nickel, stainless steel, cobalt, tantalum, and mixtures and alloys thereof.
44. The procedure of claim 43 wherein said cutting member comprises titanium and nickel.
- 30 45. The procedure of claim 35 wherein said cutting member is an RF cutter utilizing radio-frequency energy to cut said discrete tissue mass and wherein said step of rotating said

cutting member and said cutting surface to form a discrete tissue mass includes the imposition of radio-frequency energy to effectuate said cutting.

46. The procedure of claim 35 wherein said cutting member is a mechanical blade.

47. The procedure of claim 46 wherein said mechanical blade cutting member is vibrated.

48. The procedure of claim 35 wherein said cutting member is an RF cutter having a sharp mechanical cutting surface.

49. The procedure of claim 35 wherein said cutting member is an ultrasound cutter utilizing high frequency audio energy to cut said discrete tissue mass and further including the step of applying ultrasound energy to said cutting member.

50. The procedure of claim 35 wherein said trocar includes a slot and said cutting surface fits in said trocar slot.

51. The procedure of claim 35 wherein said tissue removal assembly further comprises a rotatable auger situated within said tubular tissue removal member for moving excised tissue along said tubular tissue removal member to said tissue exit port and wherein said procedure includes rotating said auger to remove excised tissue.

52. The procedure of claim 51 further comprising the step of reconstituting the excised tissue to the form as found prior to the cutting step.

53. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

introducing, to a position adjacent a selected internal tissue region, a tissue removal member and a cutting member rotatable with respect to said tubular tissue removal member,

rotating and translating said cutting member to form a helically cut discrete tissue mass in said selected internal tissue region having a diameter generally greater than said

tissue removal member, and

removing said discrete tissue mass through said tissue removal member.

54. The procedure of claim 53 including the step of introducing RF energy to said cutting
5 member to form said helical cut in said discrete tissue mass.

55. The procedure of claim 53 wherein said cutting member is a mechanical blade.

56. The procedure of claim 53 further including the step of vibrating said mechanical blade
10 cutting member.

57. The procedure of claim 53 further including the step of moving excised tissue along
said tubular tissue removal member using a rotatable auger situated within said removal
member by rotating said auger.

15 58. The procedure of claim 57 further comprising the step of reconstituting the excised
tissue to the form as found prior to the cutting step.

59. The procedure of claim 53 wherein the cutting member comprises a hollow shaft, and
20 wherein said introducing step further comprises introducing the hollow shaft over a
distal end of a localization wire having a distal end proximate the selected internal
tissue region.

60. The procedure of claim 59 wherein said rotating and translating step further comprises
25 rotating the cutting member about the localization wire and translating the cutting
member along the localization wire.

61. The procedure of claim 59 and further including a step of removing the localization
wire through the tissue removal member.

30 62. The procedure of claim 59 wherein said step of removing the localization wire occurs
simultaneously with said step of removing the tissue.

63. A procedure for cutting tissue from a selected internal tissue region marked with a localization wire, comprising the steps of:

5 inserting a distal end of the localization wire into a hollow shaft of a cutting member, wherein the hollow shaft has an inner diameter approximately equal to the width of the localization wire;

 translating the cutting member over the localization wire to the selected internal tissue region; and

 cutting a discrete tissue mass in the selected internal tissue region.

10 64. The tissue removal assembly of claim 1 wherein said cutting member further includes a hollow shaft extending between said tissue removal assembly proximal end and said tissue removal assembly distal end, wherein said hollow shaft includes an open distal end.

15 65. The tissue removal assembly of claim 64 wherein said tubular tissue removal member further includes a shaft passageway generally parallel to said tubular tissue removal member longitudinal axis, wherein said cutting member shaft is slideable within and rotatable within said shaft passageway.

20 66. The tissue removal assembly of claim 65 wherein said shaft passageway is exterior to said tissue removal passageway.

25 67. The tissue removal assembly of claim 22 wherein said shaft passageway is exterior to said tubular tissue removal member.

30 68. The tissue removal assembly of any one of claims 22, 23, or 67, further comprising a small lumen member and wherein said shaft passageway is located within said small lumen member and wherein said small lumen member is movable with respect to said tubular tissue removal member.

69. The tissue removal assembly of claim 69 wherein said small lumen member has a

tapered distal end.

70. The tissue removal assembly of claim 68 or 69 wherein said cutting surface is deployable through said shaft passageway.

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71. A procedure for preparing a tissue biopsy sample, comprising the steps of:
rotating a cutting member with respect to the tissue biopsy sample; and
simultaneously advancing the cutting member with respect to the tissue biopsy sample to helically cut the tissue biopsy sample.

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72. The procedure of claim 53 wherein said introducing step comprises introducing the cutting member to a position proximal of the selected internal tissue region; and wherein said rotating and translating step includes:

rotating the cutting member to first form a circular cut proximal of said selected internal tissue region,
then advancing and rotating the cutting member through the selected internal tissue region to form a helically cut discrete tissue mass in the selected internal tissue region,
and
then rotating the cutting member to form a circular cut distal of the selected internal tissue region.

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73. The procedure of claim 53 wherein said introducing step comprises introducing the cutting member to a position distal of the selected internal tissue region; and wherein said rotating and translating step includes:

rotating the cutting member to first form a circular cut distal of the selected internal tissue region,
then pulling back and rotating the cutting member through the selected internal tissue region to form a helically cut discrete tissue mass in the selected internal tissue region,
and
then rotating the cutting member to form a circular cut proximal of the selected internal tissue region.

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74. The procedure of claim 53 wherein said step of removing the discrete tissue mass occurs simultaneously with said step of rotating and translating the cutting member.

5 75. The procedure of claim 53 wherein said step of removing the discrete tissue mass occurs after said step of rotating and translating the cutting member.

76. The tissue removal assembly of claim 1 wherein said cutting surface is serrated.

10 77. The tissue removal assembly of claim 1 wherein said cutting member includes a shaft extending between said cutting surface and said tubular tissue removal member proximal end and wherein at least a portion of said cutting surface is skew to said shaft.

15 78. The tissue removal assembly of claim 1 wherein, upon rotation and/or translation of said cutting member, said cutting surface follows a cutting path, and wherein said cutting surface is nonperpendicular to said cutting path.

20 79. The tissue removal assembly of claim 64 wherein said cutting member hollow shaft has an inner surface and wherein said inner surface is electrically and/or thermally insulated.

25 80. The tissue removal assembly of claim 64 further comprising a localization wire having a proximal end and a distal end, wherein said localization wire distal end is adapted for placement within said selected tissue and wherein said localization wire proximal end is adapted for placement within said cutting member hollow shaft, and wherein said localization wire is electrically and/or thermally insulated.

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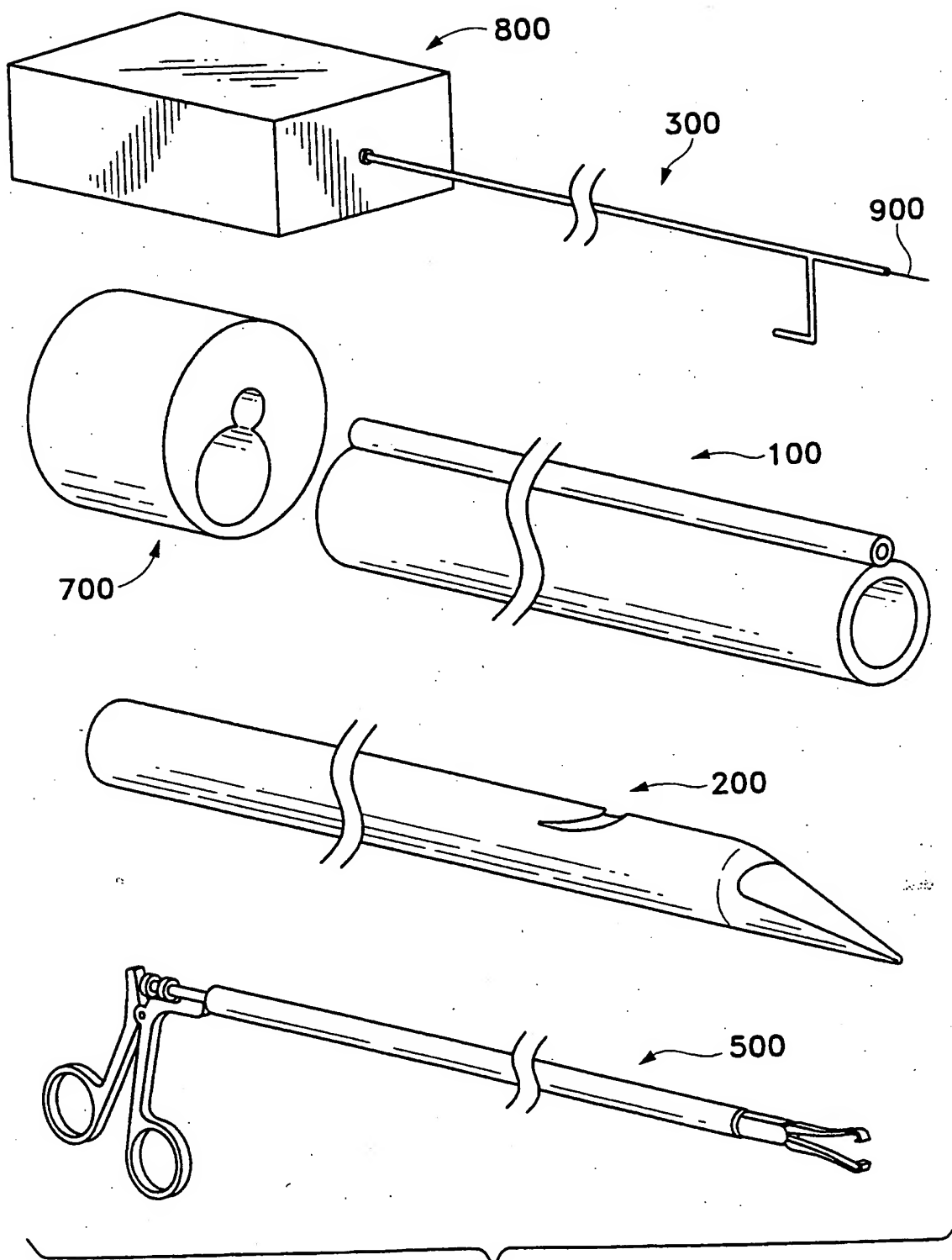
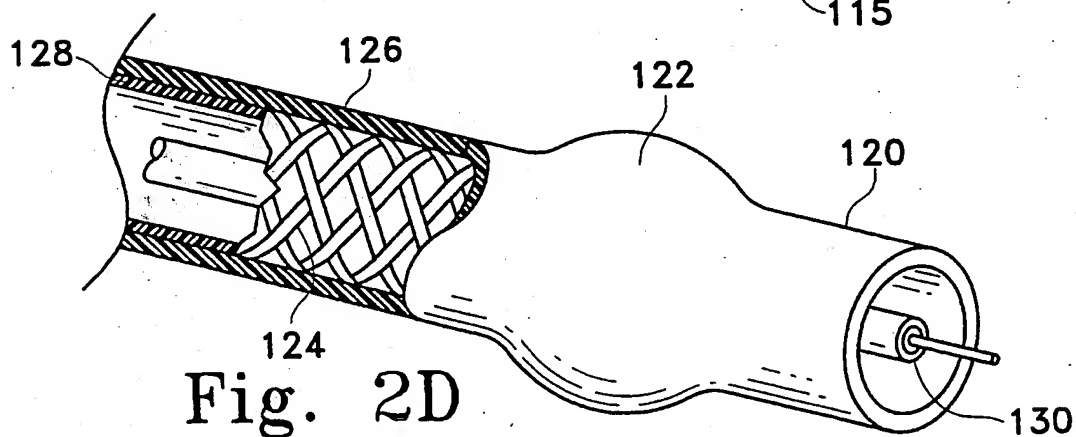
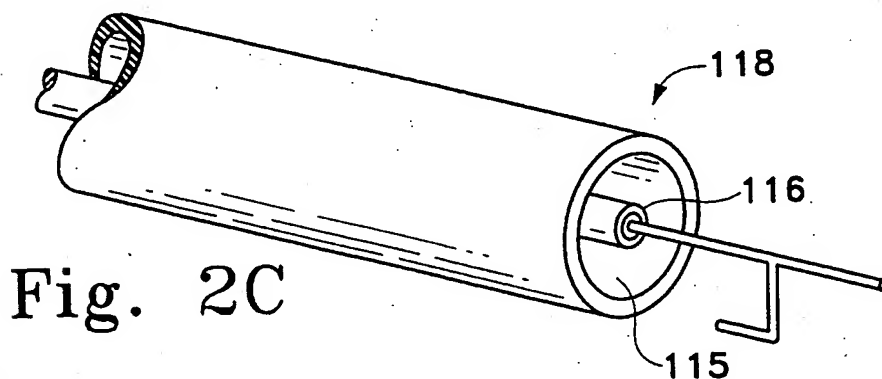
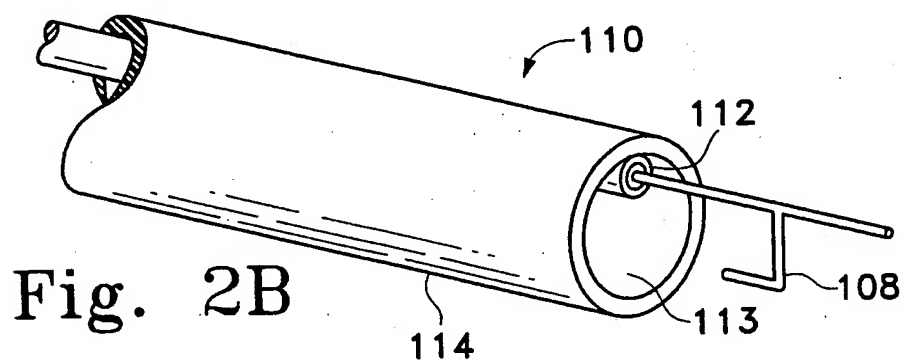
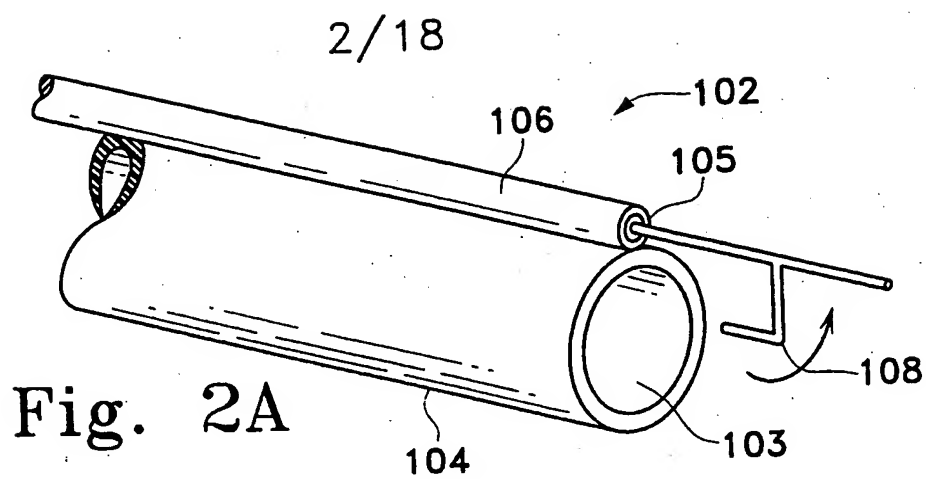
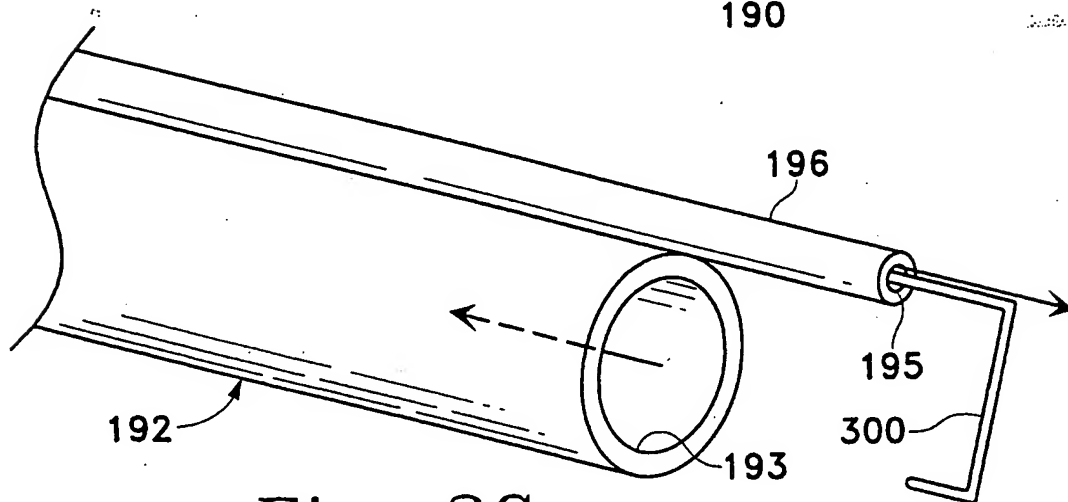
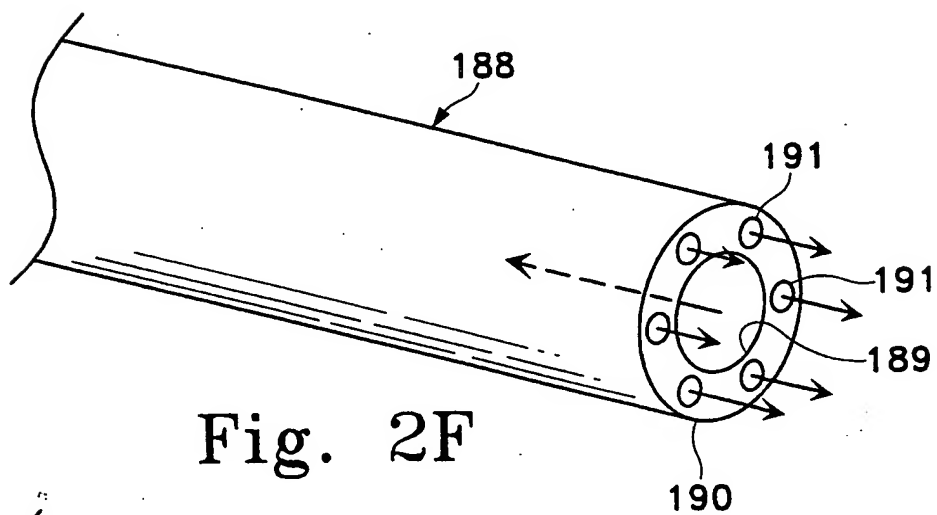
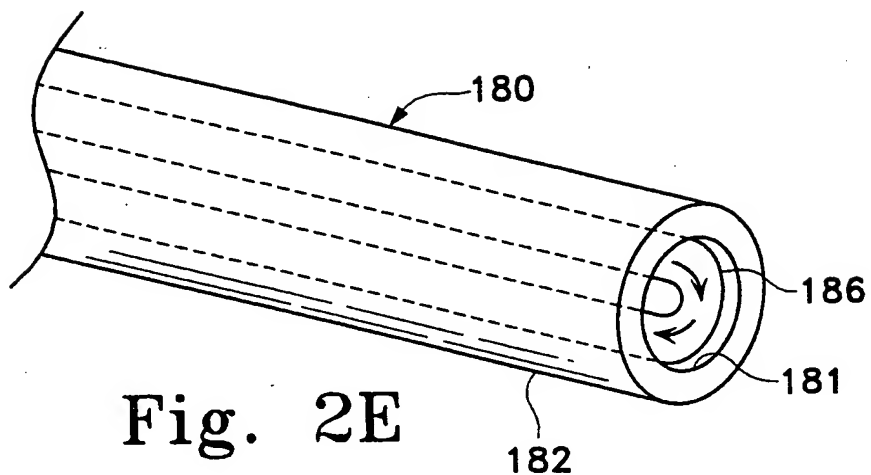


Fig. 1



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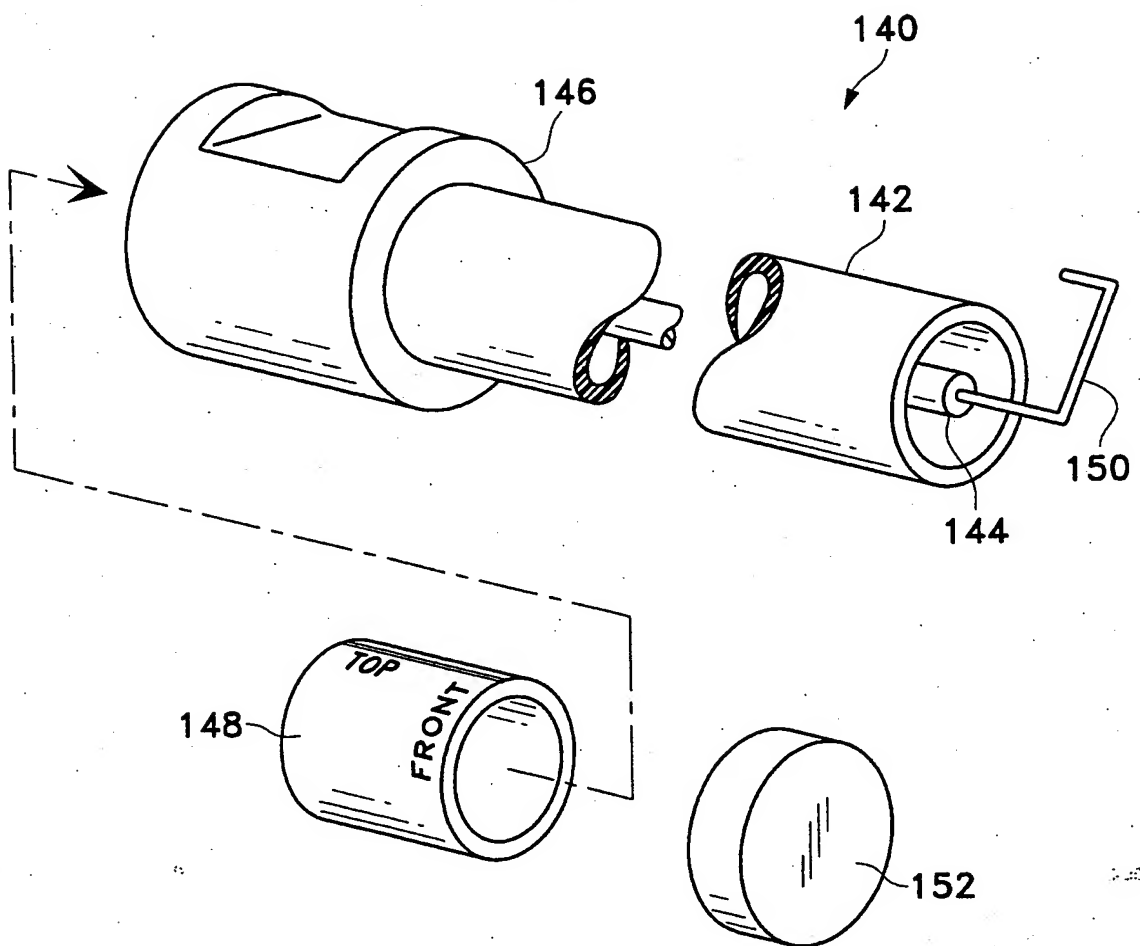
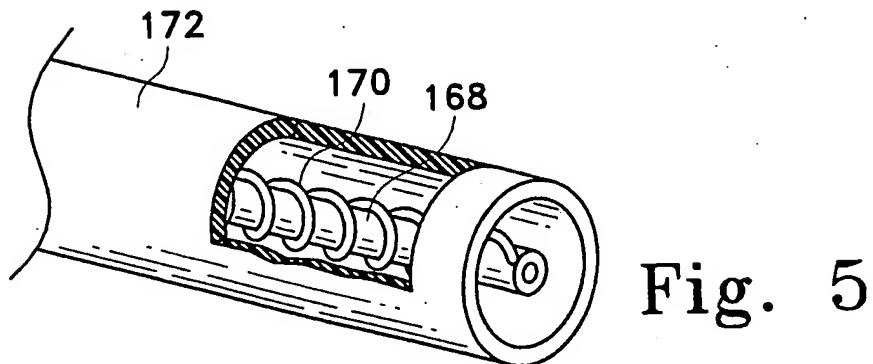
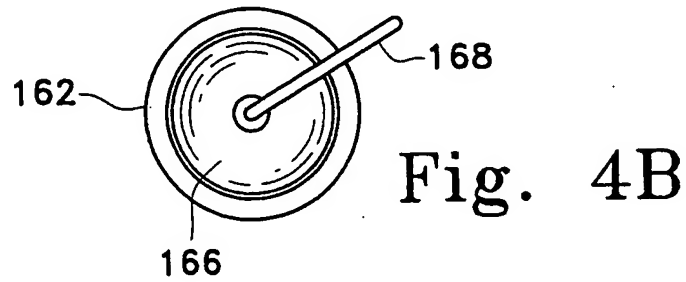
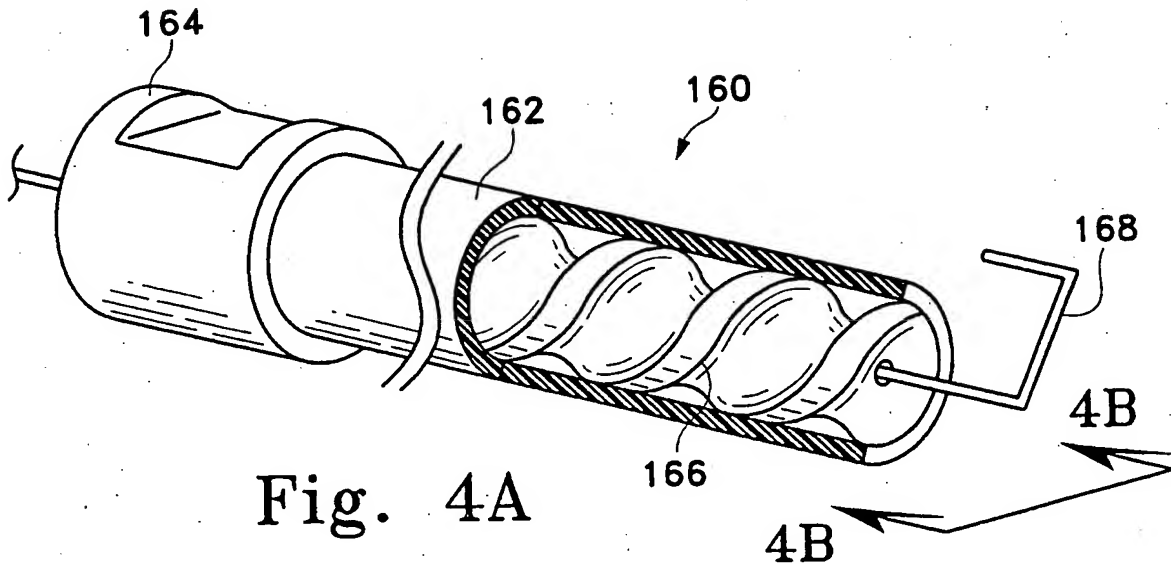


Fig. 3

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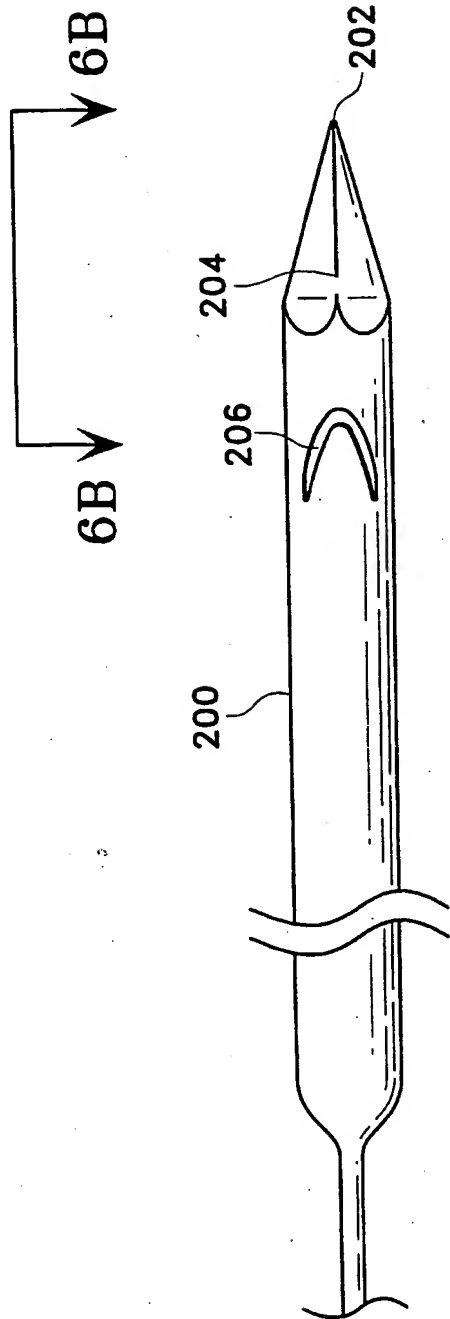


Fig. 6A

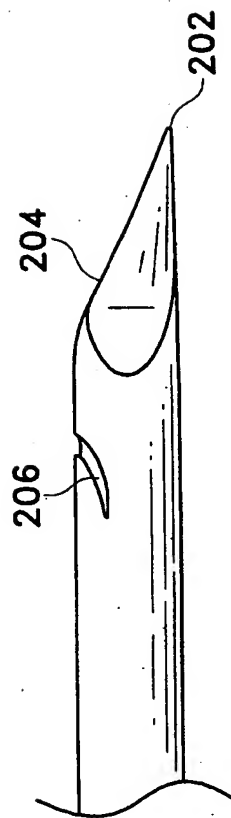


Fig. 6B

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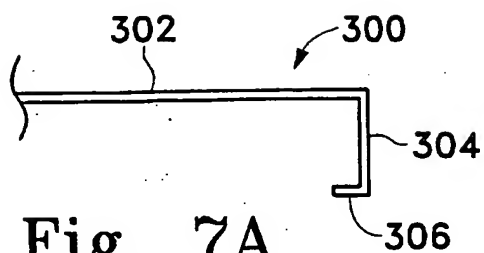


Fig. 7A

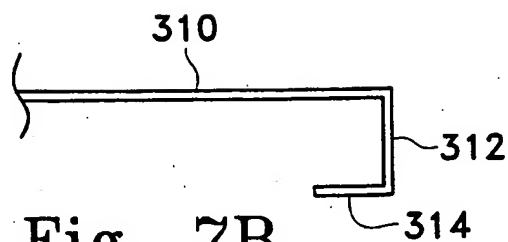


Fig. 7B

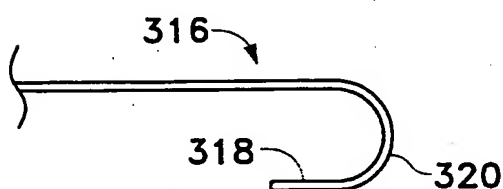


Fig. 7C

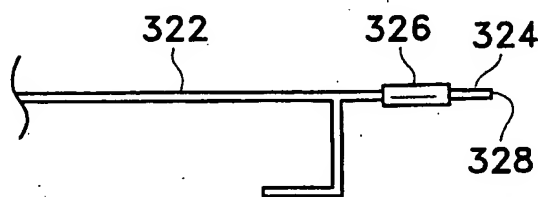


Fig. 7D

Fig. 8A

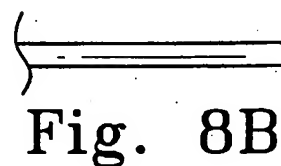
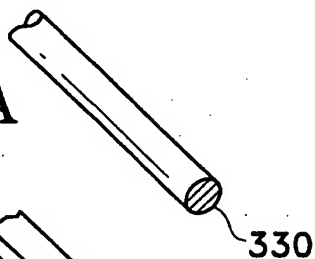


Fig. 8B

Fig. 9A

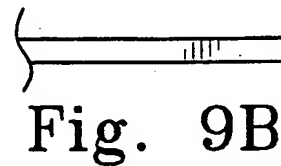
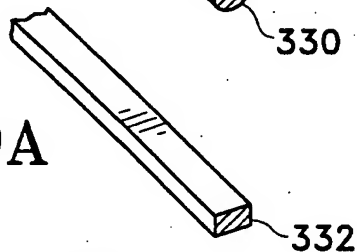


Fig. 9B

Fig. 10A

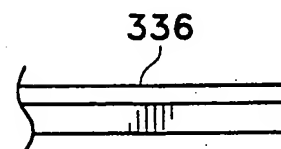
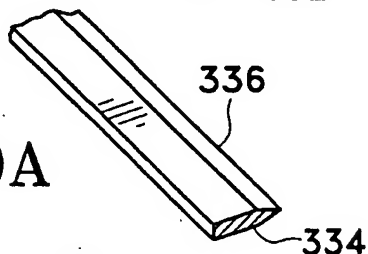


Fig. 10B

Fig. 11A

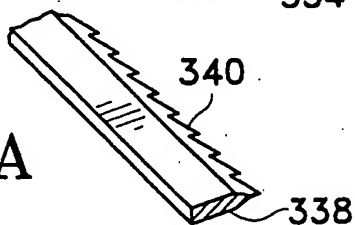


Fig. 11B

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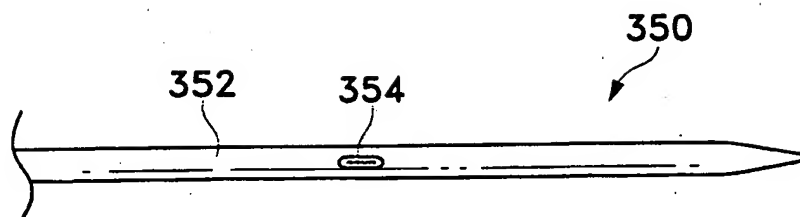


Fig. 12A

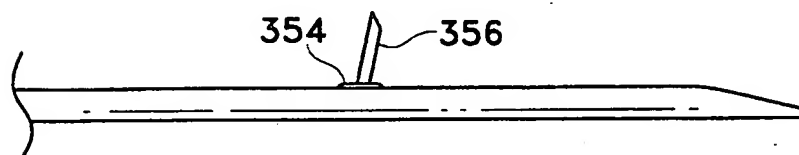


Fig. 12B

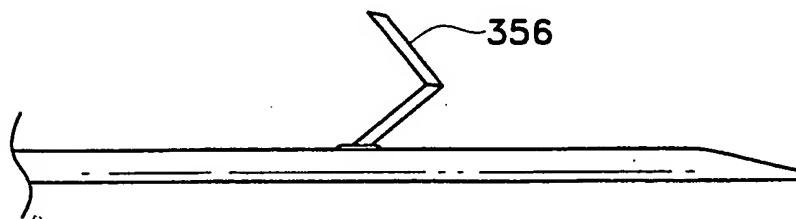


Fig. 12C

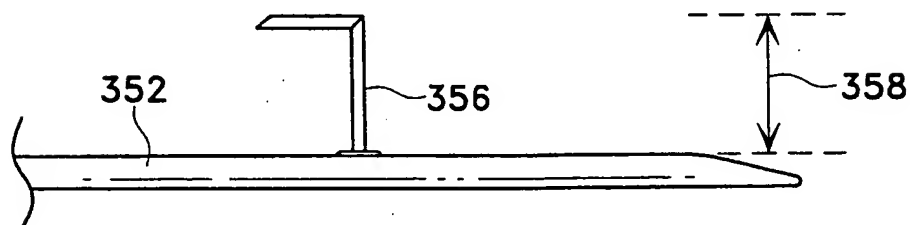
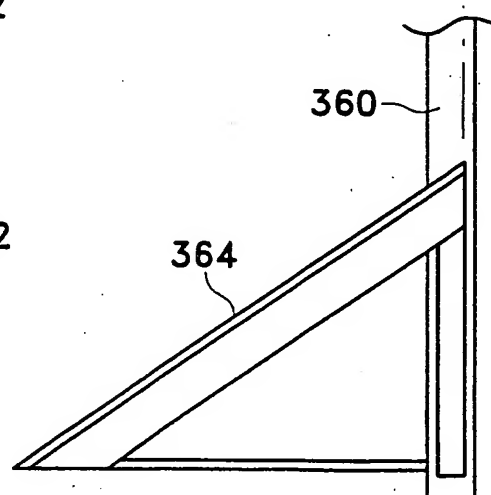
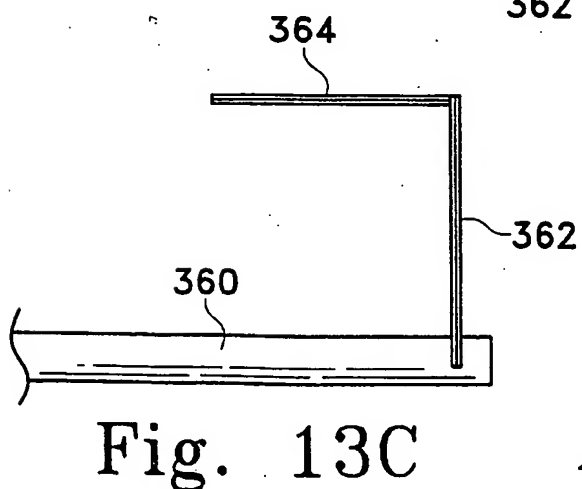
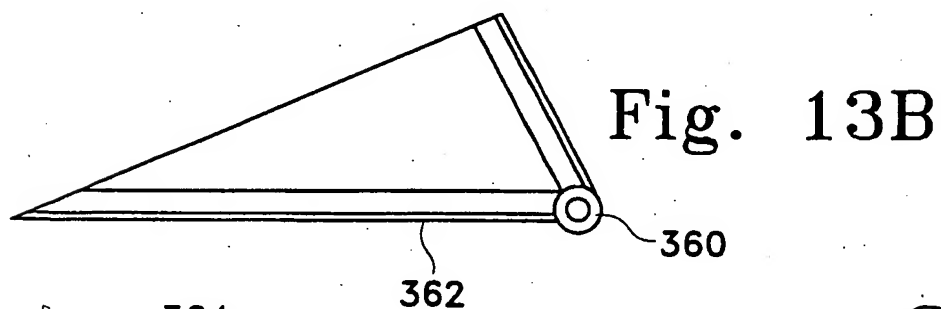
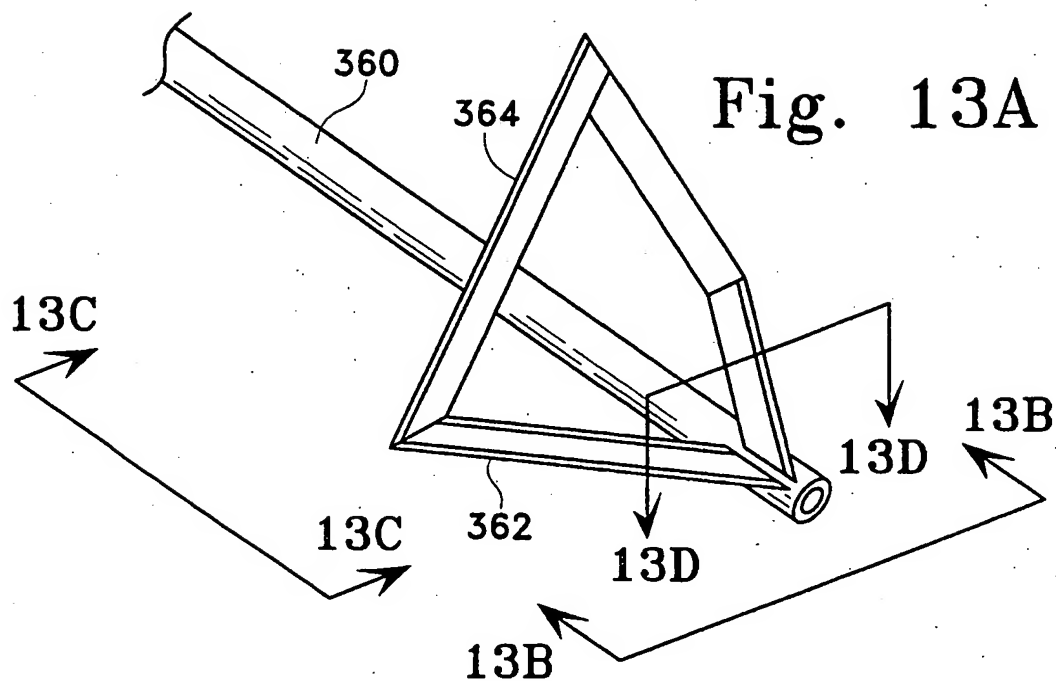
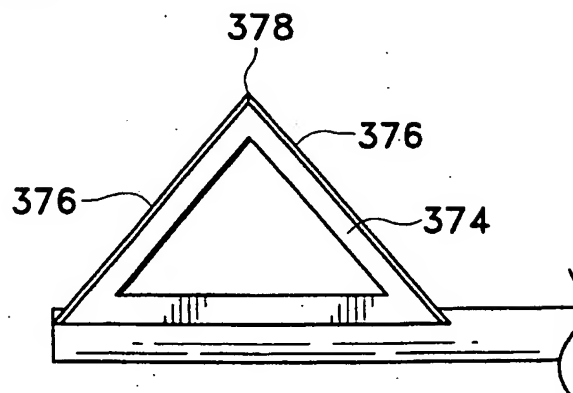
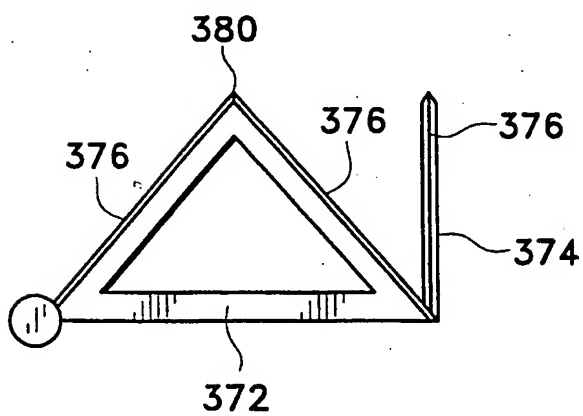
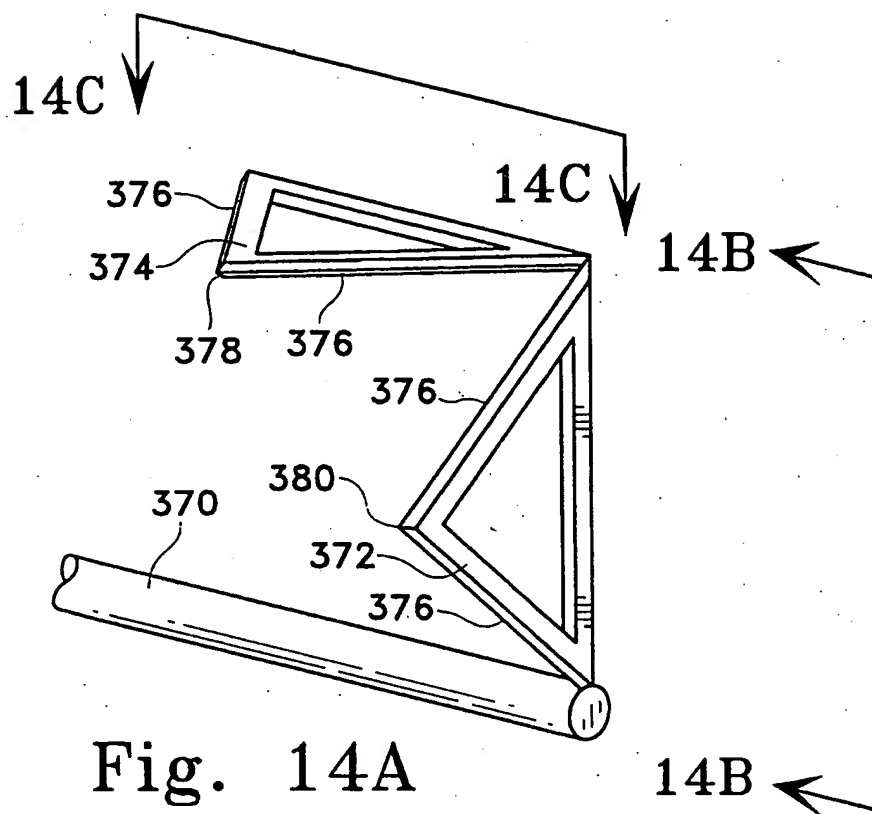


Fig. 12D

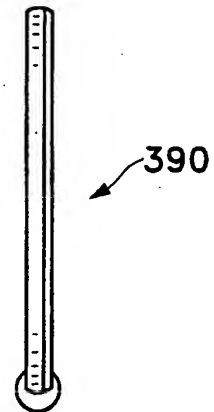
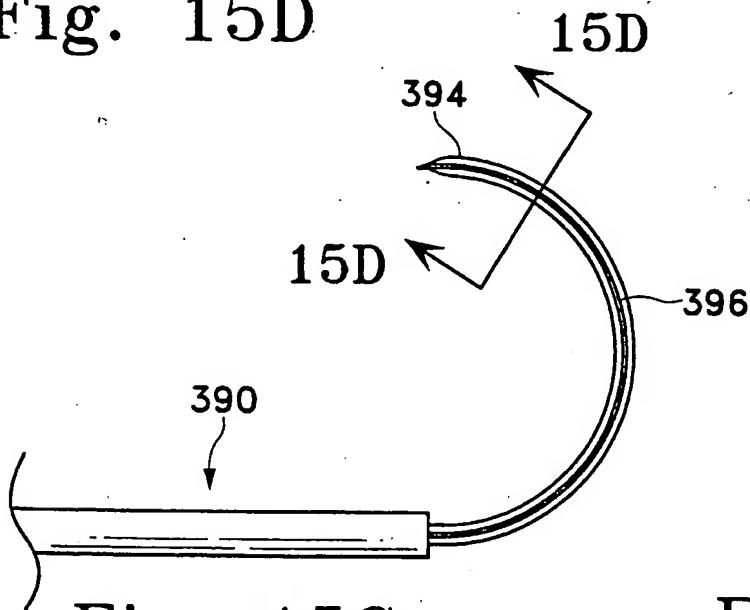
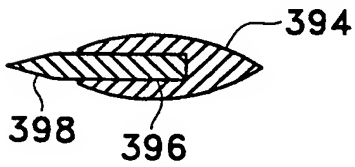
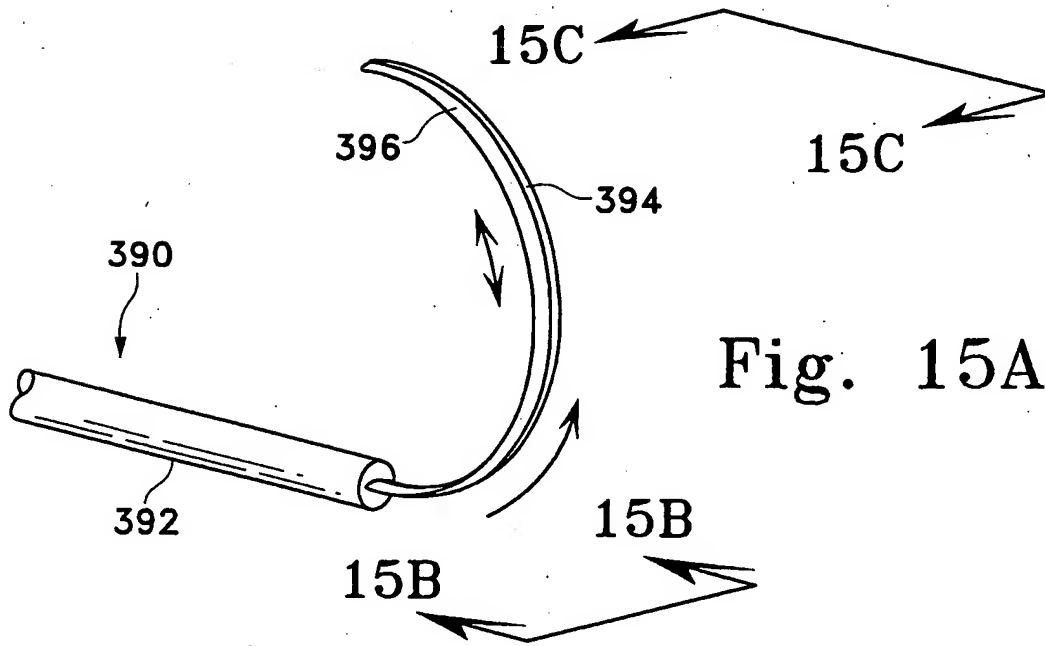
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Fig. 16

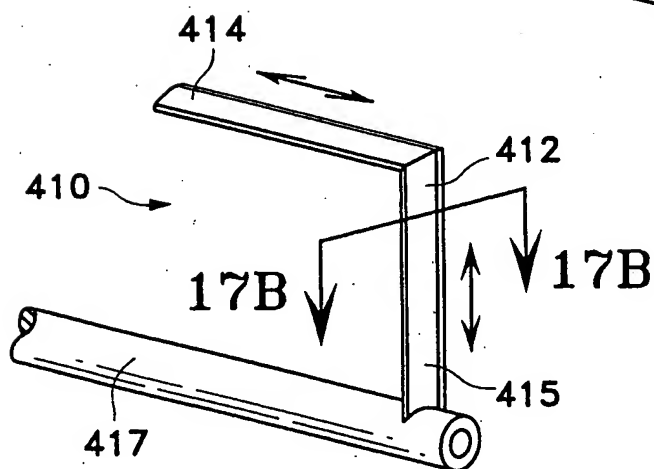
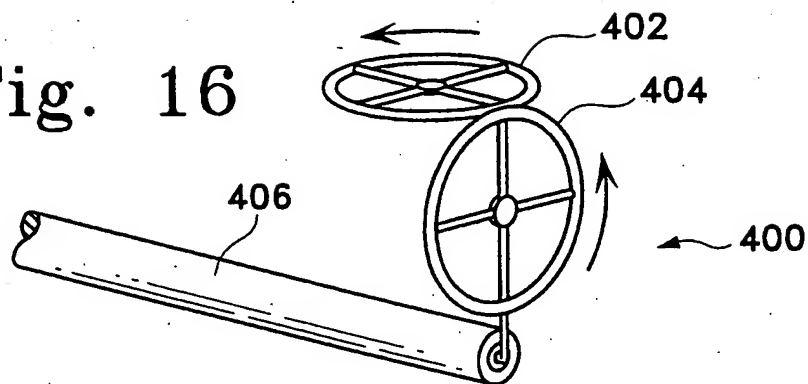


Fig. 17A

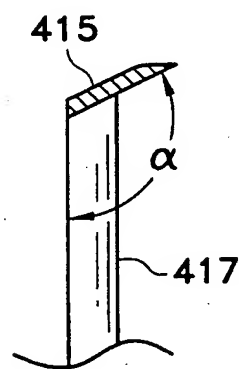


Fig. 17B

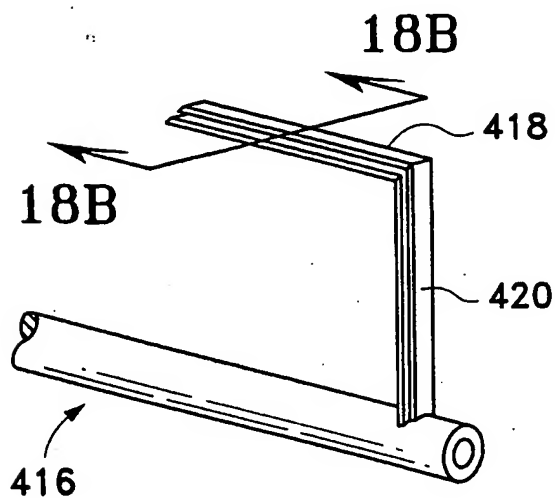


Fig. 18A

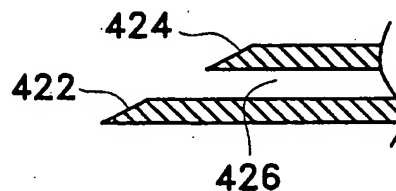
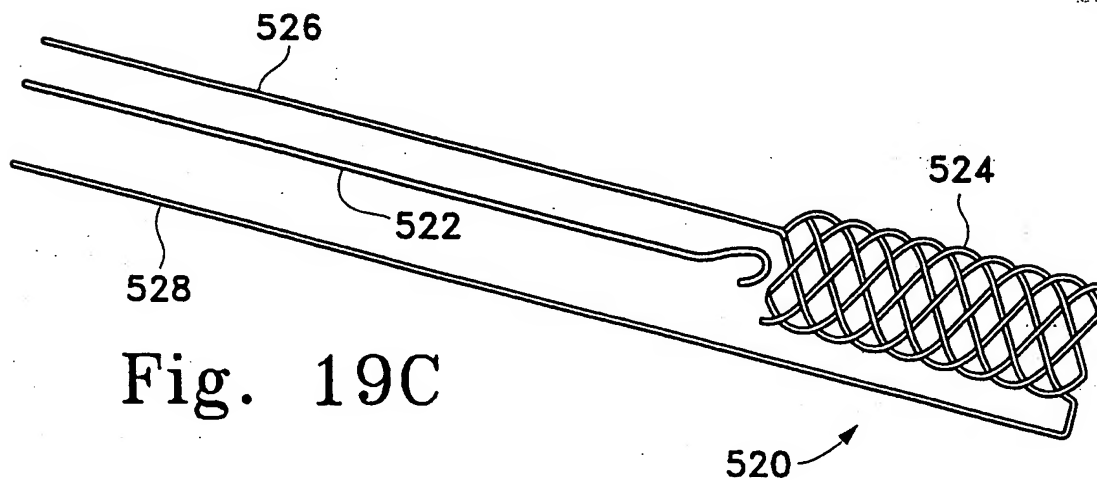
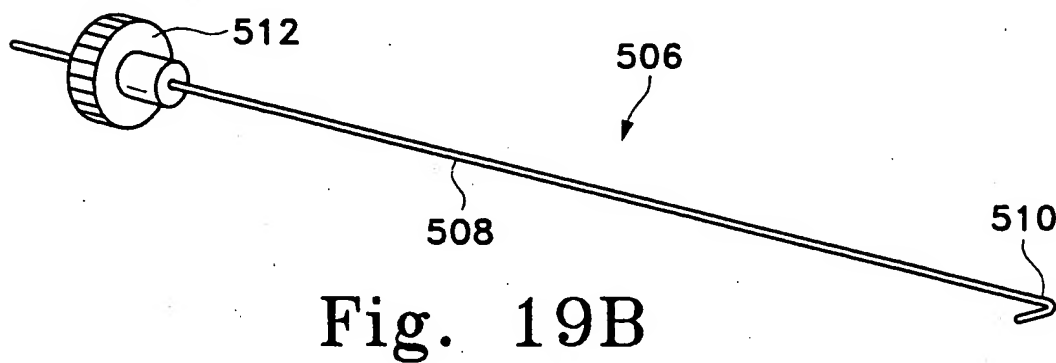
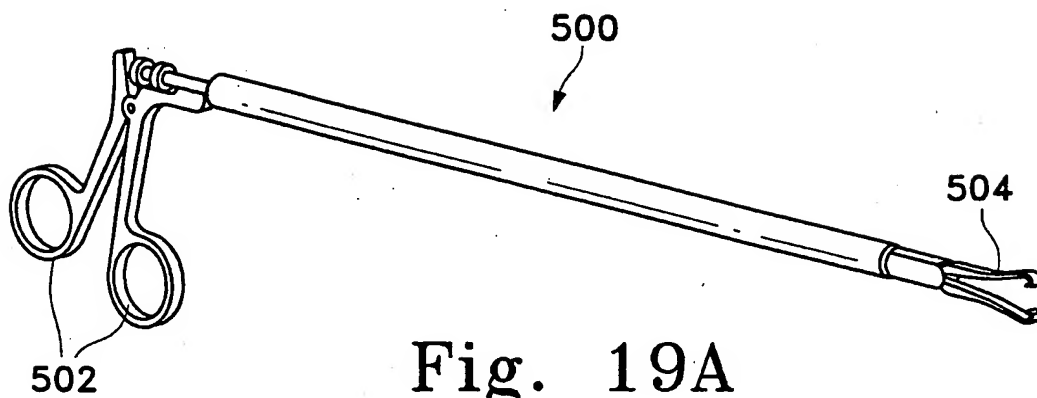


Fig. 18B

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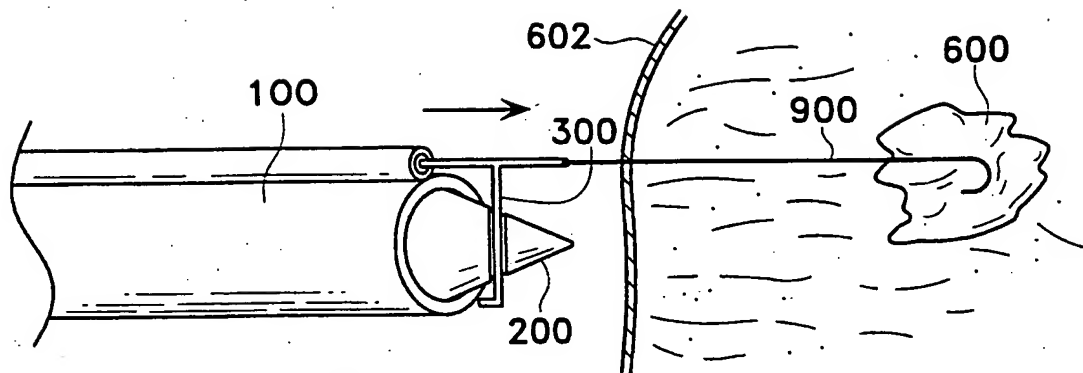


Fig. 20A

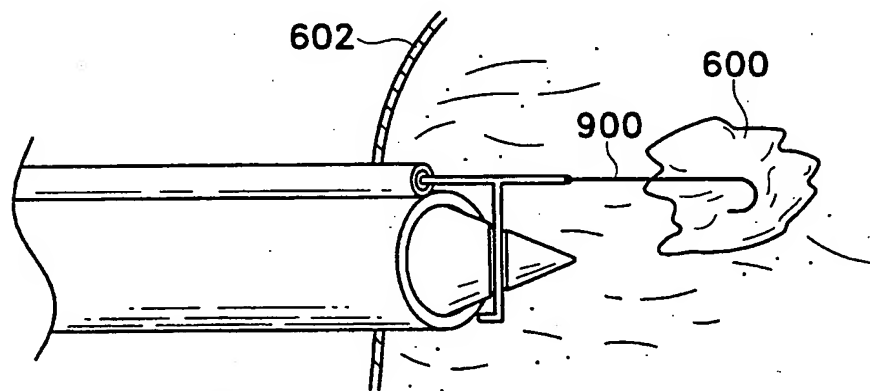


Fig. 20B

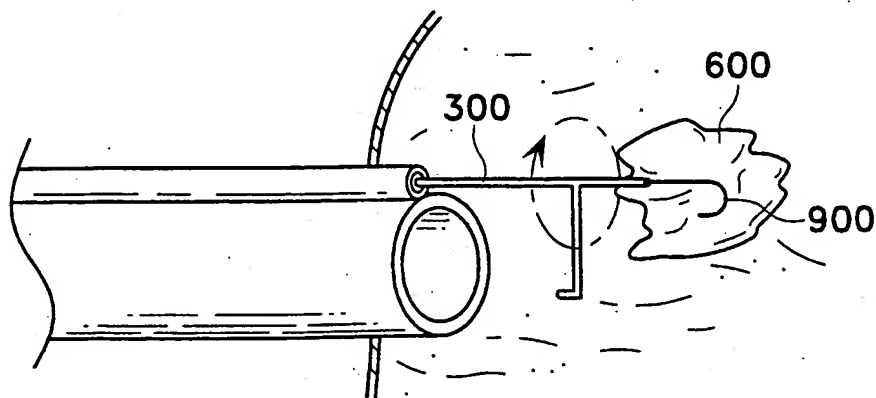


Fig. 20C

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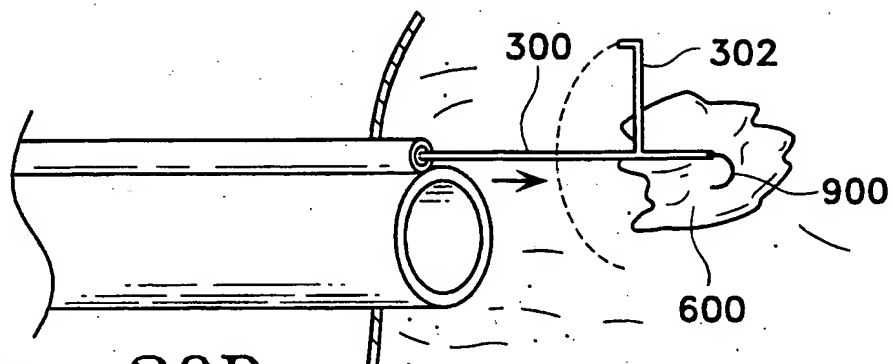


Fig. 20D

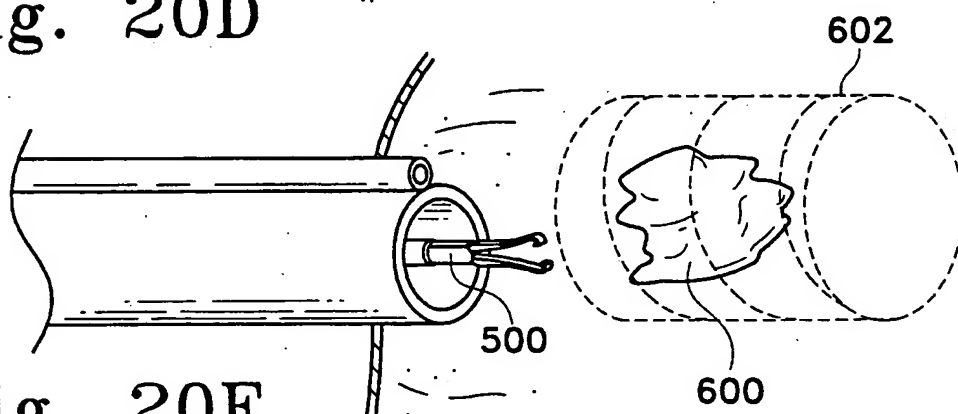


Fig. 20E

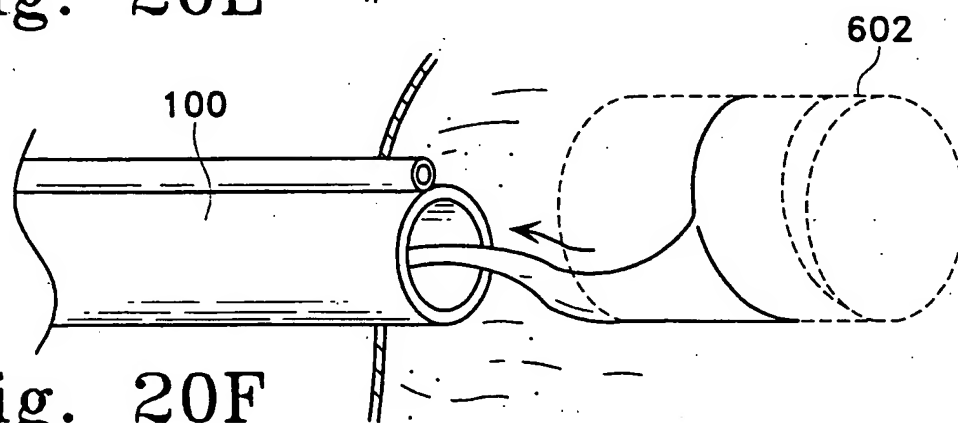


Fig. 20F

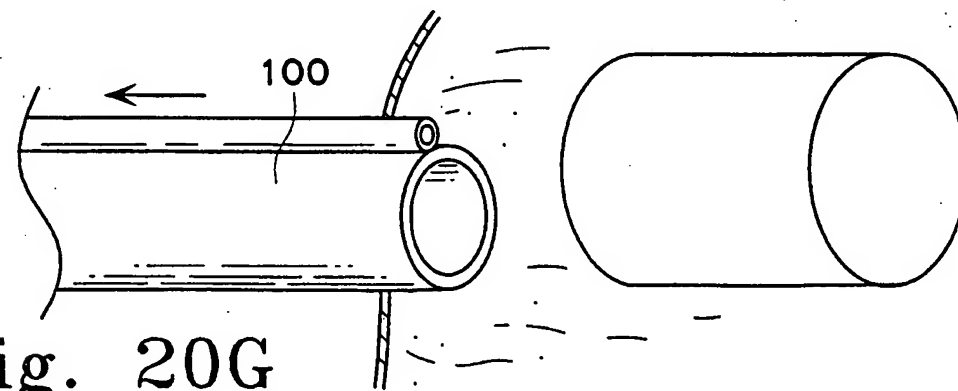


Fig. 20G

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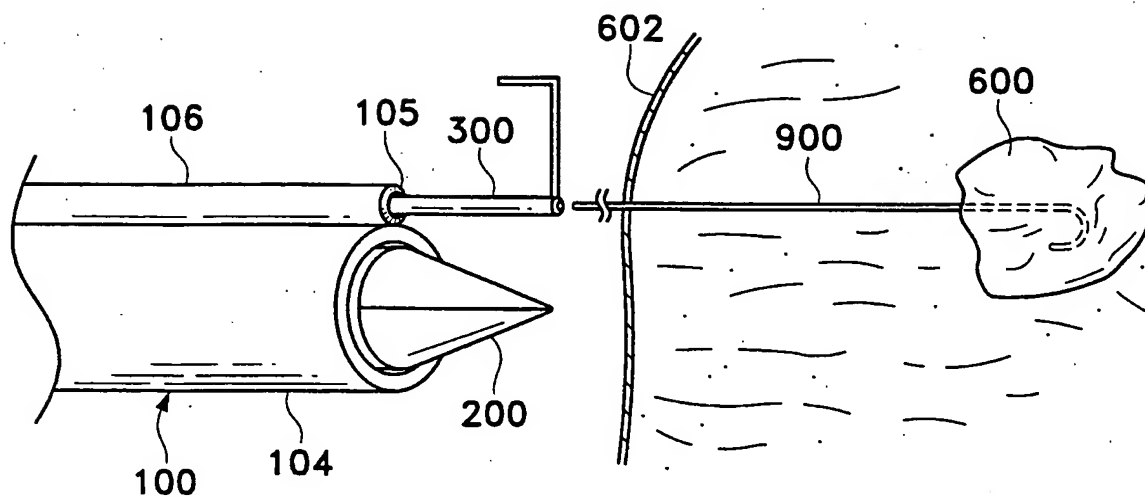


Fig. 21A

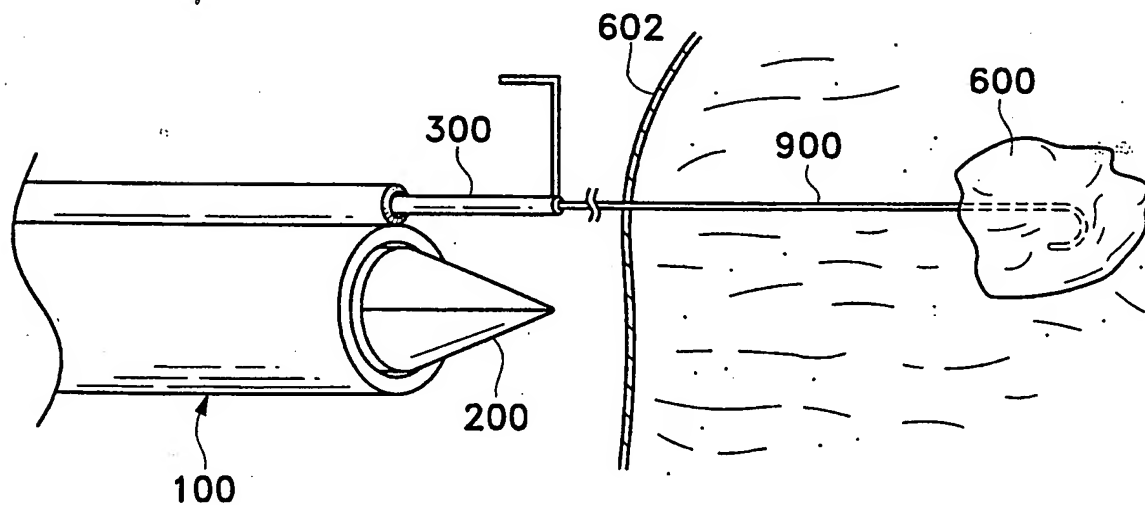


Fig. 21B

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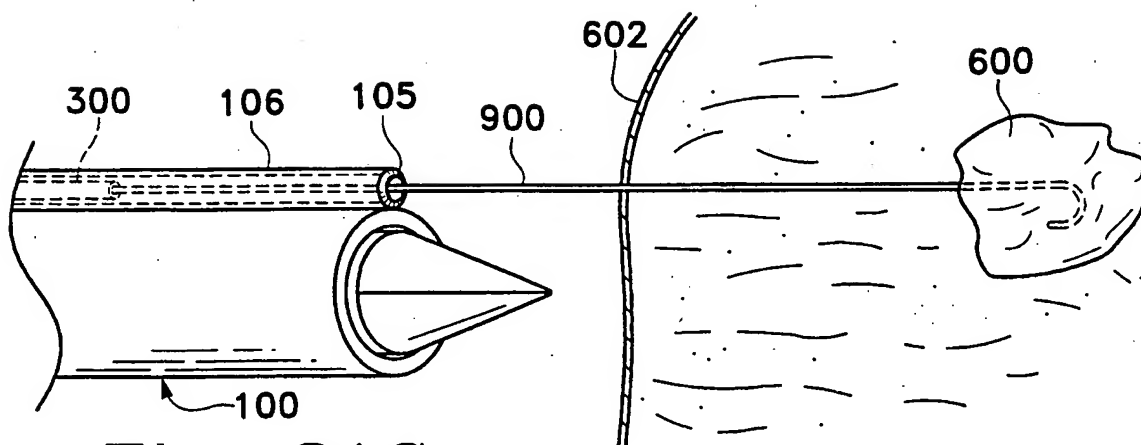


Fig. 21C

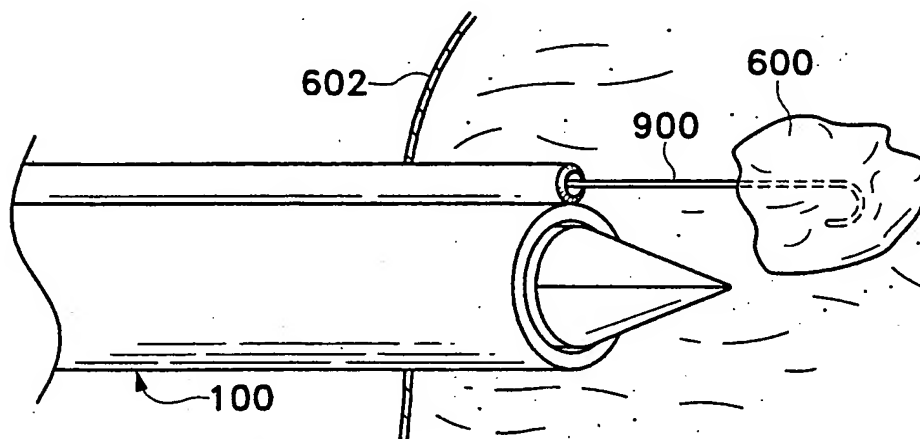


Fig. 21D

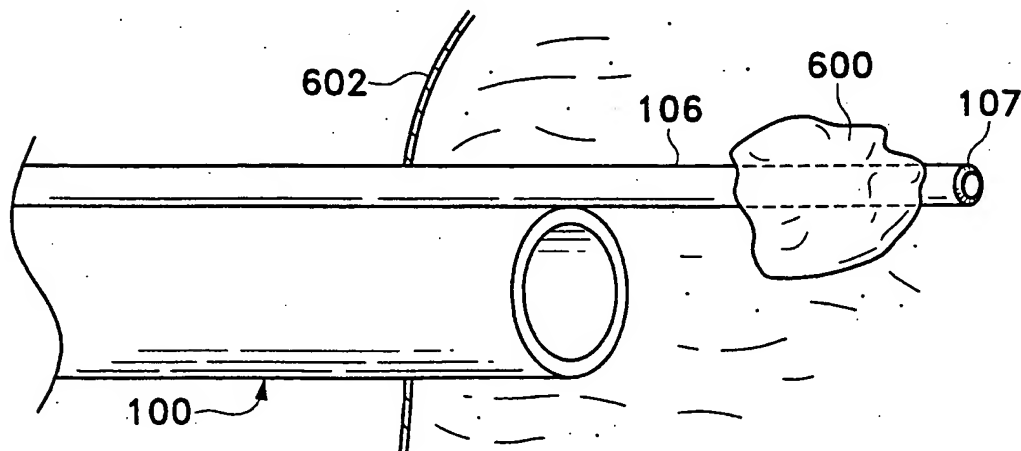


Fig. 21E

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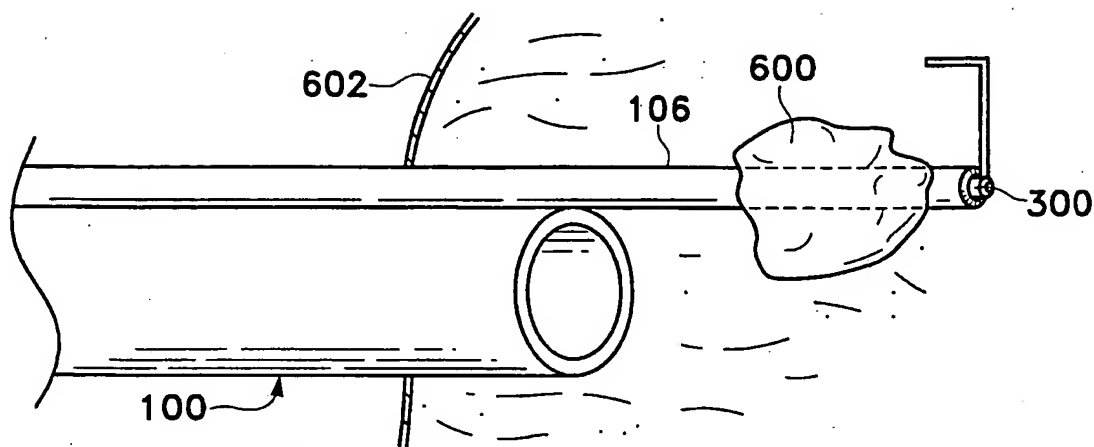


Fig. 21F

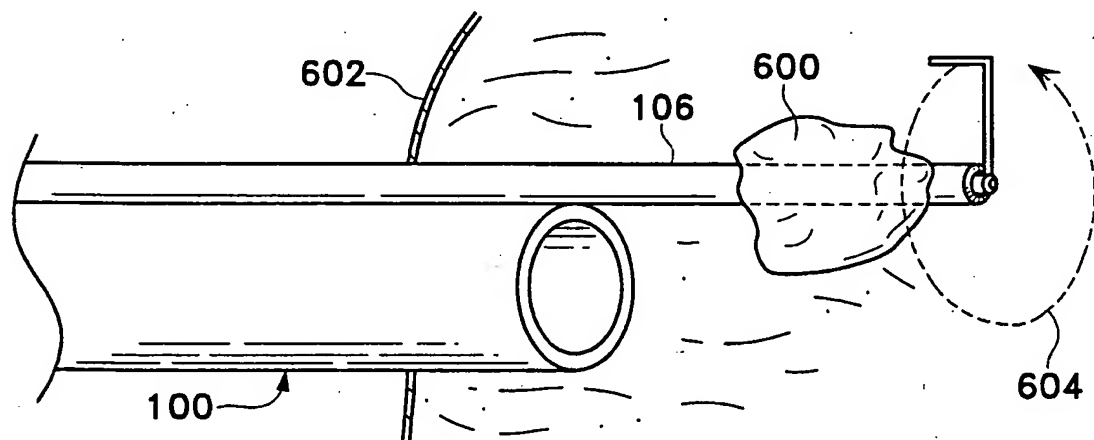


Fig. 21G

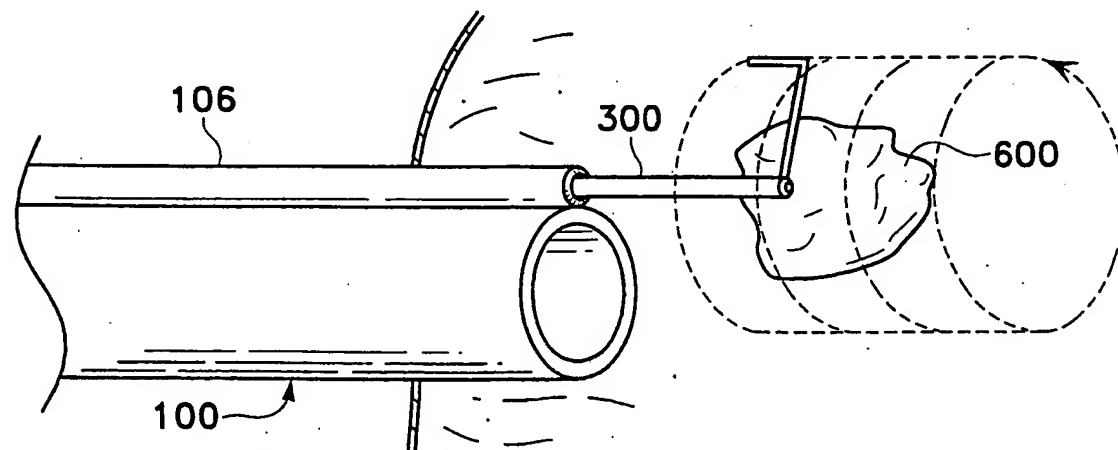


Fig. 21H

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/19660

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B10/00 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 729 210 A (SPENCER) 3 January 1956 (1956-01-03) column 3, last line; figures 2-4	1
A	US 4 461 305 A (CIBLEY) 24 July 1984 (1984-07-24) abstract; figure 10	1
A	US 5 709 697 A (RATCLIFFE) 20 January 1998 (1998-01-20) figures 25,26	1
A	US 5 611 803 A (HEAVEN) 18 March 1997 (1997-03-18) figures 8,9	1
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

17 November 1999

Date of mailing of the international search report

01/12/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/19660

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No:
A	US 3 175 554 A (STEWART) 30 March 1965 (1965-03-30) figures 10-12 ----	1
A	WO 98 08441 A (ETHICON) 5 March 1998 (1998-03-05) ----	
A	EP 0 829 232 A (CITY OF HOPE) 18 March 1998 (1998-03-18) ----	
A	US 3 732 858 A (BANCO) 15 May 1973 (1973-05-15) ----	
A	WO 95 08291 A (BOSTON) 30 March 1995 (1995-03-30) -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/19660

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 35-63, 71-75
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/19660

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2729210	A	03-01-1956	NONE	
US 4461305	A	24-07-1984	NONE	
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WO 9508291	A	30-03-1995	US 5573008 A CA 2172128 A CA 2172129 A CA 2172130 A CA 2172131 A CA 2172132 A EP 0722286 A EP 0722287 A EP 0720440 A EP 0720441 A EP 0720442 A JP 9504451 T JP 9502898 T JP 9502907 T JP 9503404 T JP 9502909 T WO 9508944 A WO 9508945 A WO 9508946 A WO 9508292 A US 5840044 A US 5823971 A	12-11-1996 06-04-1995 06-04-1995 30-03-1995 06-04-1995 30-03-1995 24-07-1996 24-07-1996 10-07-1996 10-07-1996 10-07-1996 06-05-1997 25-03-1997 25-03-1997 08-04-1997 25-03-1997 06-04-1995 06-04-1995 06-04-1995 30-03-1995 24-11-1998 20-10-1998